UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CIVIL ACTION NO 16-MD-2738(FLW)(LHG)

IN RE JOHNSON & JOHNSON POWDER PRODUCTS MARKETING, SALES PRACTICES.	:	DAUBERT HEARING JULY 31, 2019 VOLUME 8

CLARKSON S. FISHER UNITED STATES COURTHOUSE
402 EAST STATE STREET, TRENTON, NJ 08608

B E F O R E: THE HONORABLE FREDA L. WOLFSON, USDJ

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BY: P. LEIGH O'DELL, ESQUIRE (ALABAMA)
MARGARET M. THOMPSON, ESQUIRE (ALABAMA)
DAVID DEARING, ESQUIRE (ALABAMA)
-and-
ASHCRAFT & GEREL, ESQUIRES
BY: MICHELLE A. PARFITT, ESQUIRE (VIRGINIA)
On behalf of Plaintiffs Steering Committee

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BY: SUSAN M. SHARKO, ESQUIRE (NEW JERSEY)
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SKADDEN, ARPS, SLATE, MEAGHER & FLOM, ESQUIRES
BY: JOHN H. BEISNER, ESQUIRE (WASHINGTON, D.C.)
-and-
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BY: BART H. WILLIAMS, ESQUIRE (CALIFORNIA)
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On behalf of Defendant Johnson & Johnson

(Continued.)

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On Behalf of Defendant Personal Care Products Council

M O R N I N G S E S S I O N

(In open court.)

THE DEPUTY CLERK: All rise.

THE COURT: Thank you. Good morning. Everyone may be seated.

MR. WILLIAMS: Your Honor, the defense calls Dr. Cheryl Saenz to the stand.

CHERYL C. SAENZ, sworn.

DIRECT EXAMINATION

BY MR. WILLIAMS:

Q. Good morning, Dr. Saenz.

A. Good morning.

Q. Let me just orient you. There is a notebook in front of you. We will be referring to that from time to time. There is also a bound volume that has your report in it and your CV, and things like that, in case you have to refer to that more than once.

So let's get started.

Dr. Saenz, what kind of physician are you?

A. I'm a gynecologic oncologist.

Q. How long have you been treating woman with gynecologic cancers?

A. I have been in practice for a little bit over 20 years, and prior to that I did a fellowship in gynecologic oncology for three years.
Q. Where do you presently practice medicine?
A. I presently practice at the University of California San Diego.
Q. How long have you been there?
A. Almost 21 years.
Q. Let's touch briefly on your educational background. Where did you attend medical school?
A. I went to medical school at the University of California, Irvine.
Q. And your residency?
A. My residency was at the University of California, San Diego.
Q. And what was that in?
A. That was in reproductive medicine, also known as obstetrics and gynecology.
Q. And, next, as I understand it, you completed a fellowship. Is that right?
A. Yes, that's correct. I completed a fellowship in gynecologic oncology at Memorial Sloan Kettering Cancer Center.
Q. How many years was that fellowship program?
A. That fellowship was three years.

Q. What is your current title at UCSD?
A. I am a clinical professor in gynecologic oncology in the Department of Obstetrics, Gynecology and Reproductive Sciences.
Q. Does that job involve teaching?
A. Yes.
Q. And whom do you teach?
A. I teach medical students, I teach residents, and I teach fellows.
Q. In the course of your teaching, do you discuss risk factors for developing ovarian cancer with the medical students and physicians that you are training?
A. All the time.
Q. What ovarian cancer risks do you teach them about?
A. Specifically, I teach them about risk factors such as age because ovarian cancer risk increases as women age. I teach them about genetic risk factors which can be inherited. I teach them about the familial risk, meaning specifically that if they have a family member that has cancer, they could be at an increased risk of developing ovarian cancer as well.
Q. Go ahead.
A. Then I teach them about their own personal history; and, specifically, if they had cancer, they

are at an increased risk.

And then we also talk about some other risk factors, such as endometriosis, hormone replacement therapy, their own reproductive history, such as whether or not they've had children or not had children, and the ages at which they had those children, as well as factors such as when they first started having their periods and when they went through menopause.

Q. In the course of your teaching, do you ever mention talc as a risk factor for developing ovarian cancer?

A. So in my lectures I do not raise the issue of talc as a risk factor for developing ovarian cancer because I do not believe that it is a risk factor for ovarian cancer. However, there are some learners that will ask me: Well, what about talc? Because they have seen news reports or read about it in another venue. And I will then discuss with them the state on the current literature on talc as a risk factor for developing ovarian cancer.

Q. When you do that, do you disclose the fact that you have done some work on behalf of parties in litigation?

A. I absolutely do. And I tell them that I

actually have served as an expert witness for the defense because oftentimes they are actually a little amazed at the fund of knowledge I have on this subject, but that's because I have done such a thorough review of the topic.

Q. When did you start getting questions from learners -- I think it's how you put it -- when did you start getting questions about talc from your students?

A. So I would say probably about two or three years ago is when I was first asked by learners about the relationship between talc and the development of ovarian cancer.

Q. Did that coincide when you started seeing reports on television?

A. I believe that it did.

Q. Could you give us an example of research that you are currently conducting?

A. The focus of my practice actually is trying to develop screening tests for the early detection of ovarian cancer. I'm sure there have been other people up here earlier this week that have testified that screening for ovarian cancer is really quite difficult, and actually at the present time, there is no effective screening for ovarian cancer.

So one of the things that I have done is partner with some of the cellular and molecular medicine folks at UCSD to try and identify some different biomarkers that may actually be secreted into the bloodstream or identified in Pap smears.

Very early on in the development of ovarian cancer, if we can identify those biomarkers, then we could save women's lives because the survival rate with Stage I ovarian cancer is much, much better than with advanced stage disease.

Q. During the course of your career, have you performed epidemiologic research?

A. I have.

Q. Can you please provide the Court with some examples of that type of research that you have done.

A. So one of the areas that we've focused on in the Division is actually endometrial cancer, and since endometrial cancer, unlike ovarian cancer, has a very good survival rate, mainly because it's detected early since women present with vaginal bleeding.

We've been focusing our efforts on: What does ultimately kill the women that are diagnosed with endometrial cancer? Because it's not the cancer -- and we've published in epidemiologic studies, that if a woman survives after two years after her diagnosis

of endometrial cancer, we have found actually it's her, what we call, comorbid conditions, meaning high blood pressure, obesity, cardiac disease, which is most likely going to be her cause of death.

So we've actually taken those epidemiologic studies that we've published and put together a survivorship program with the women with endometrial cancer to try to get them to address those other comorbid diseases and perhaps reduce their mortality.

Q. Have you ever written an article specifically on the topic of talc and ovarian cancer?

A. I have not.

Q. Why have you not published such an article?

A. I have not done any primary research in that area. Most of my research has been focused on clinical trials or things such as we discussed earlier, trying to identify a screening test for ovarian cancer.

Q. In addition to your teaching duties and research, do you also treat patients?

A. I do.

Q. What percentage of your patients are ovarian cancer patients?

A. So even though ovarian cancer is not the most common gynecologic cancer, ovarian cancer patients do

often recur, and so they stay in your practice for many, many years. This means that they end up composing a much larger percent of my practice, and so I would say that about 50 percent of my practice is composed of women that have been diagnosed with ovarian cancer.

Q. Over the course of your career, how many ovarian cancer patients have you treated, just as an estimate?

A. It's in the thousands, probably close if not over 2,000.

Q. Do all of the patients who come to see you already have a diagnosis of ovarian cancer?

A. Well, no. Most women that are ultimately diagnosed with ovarian cancer first present with a pelvic mass, and you don't know whether or not it's cancer. But there is also other reproductive cancers that I take care of in women including uterine cancer and cervical cancer, and then about, I would say, 20 percent of my practice is composed of women that are known to be high risk for the development of ovarian cancer but have not been actually diagnosed with the disease.

Q. Is prevention of ovarian cancer part of your role?

A. Absolutely.

Q. How so?
A. Well, women that present to my practice as high risk, we place them into a screening program where we obtain regular pelvic ultrasounds and CA-125s. That's a tumor marker that has been associated with ovarian cancer. We perform regular pelvic exams on these women; and if they are not actively trying to conceive, then I highly recommend that they be placed on birth control pills to decrease their risk of developing ovarian cancer because we know that this is one of the interventions that we could make that will decrease their risk by about half.

The other thing that we do for them is when they get -- again, depending on the individual mutation that they have, when there's somewhere between 35 to 40 or 40 to 45 years old, we usually recommend that they have surgery to physically remove the tubes and ovaries because that's the only intervention that's actually been shown to improve survival in these women.

Q. Do you ask your patients whether they currently use or have used talcum powder in the perineal area?
A. I do not.
Q. Why not?
A. Because talc is not a known risk factor for the

development of ovarian cancer.
Q. Have you ever counseled a patient not to use talc?
A. I have not.
Q. Why not?
A. Because talc is not a known risk factor for the development of ovarian cancer, nor does it cause ovarian cancer.
Q. Now, if you believed, based on your review of the scientific literature and your training and experience as a gynecological oncologist that the perineal use of talc did in fact cause or contribute to ovarian cancer, would you tell your patients not to use talcum powder?
A. I absolutely would, but it does not cause ovarian cancer, so I do not tell them that.
Q. Let's turn to your opinions in this case.
We asked you to consider whether perineal use of talcum powder products causes ovarian cancer. Is that right?
A. That's correct.
Q. In your opinion, does the use of talcum powder in the perineal area cause ovarian cancer?
A. In my opinion, perineal application of talcum powder does not cause ovarian cancer.

Q. In your experience -- strike that.

In your expert opinion -- let me ask you this. How did you go about your task of figuring out the answer to that question?

A. I went about researching this question as to whether or not talc is a risk factor for the development of ovarian cancer, much like I would go about asking any other question in the field of gynecologic oncology. I did a very extensive literature search. I reviewed somewhere around 30 case-control studies. I reviewed the four published cohort studies. I reviewed seven meta-analyses and one pooled analysis.

I went back and looked at the literature surrounding what are the known established risk factors for ovarian cancer, and put together a report based on that research.

I also relied very heavily upon my experience in the field practicing in the subspecialty of gynecologic oncology for almost 25 years now, and considered all of the patients that I have taken care of that have had the diagnosis of ovarian cancer, as well as the women that are in my practice and that I've taken care of that are at high risk for developing ovarian cancer, including all of the slides

that I've looked at from their surgeries, all of the findings that I find when I'm operating. I relied upon the breadth and depth of my experience.

Q. We'll get into some of those findings that you've had, specifically, with regard to inflammation, a little bit later. But for now, I would like to ask you a question about the limitations or the impact on your opinions of the asbestos.

Let me ask you just this one question for now.

Now, you understand that the defense in this case vigorously disputes the methodology and replicability and reliability of the analyses that were done by Dr. Longo's analysts. You understand that. Correct?

A. I understand that.

Q. If there were in fact trace elements of asbestos in Johnson's Baby Powder, would that change any of the opinions that you have given just a few moments ago that talc does not cause ovarian cancer?

A. No, it would not.

Q. Why not?

A. The literature that is the appropriate literature and the review that is the appropriate review to do in this case involves the application of talcum powder to the perineum, and no matter what is

in that talcum powder, if that was causing ovarian cancer, then the literature would show an increased risk of developing ovarian cancer with perineal application of talc, and it does not.

So the constituents of the product don't matter. The literature that needs to be examined and the only literature in my opinion that matters is the talcum powder literature.

Q. For purposes of your analysis of that literature, did you focus on considerations of strength and consistency of this association?

A. Absolutely. The same way that I would in my practice analyzing any other question. I looked at the strength of the association. I looked at the consistency of the literature, both comparing the literature to itself, study to study, type of study to study, as well as the consistency within individual study reports.

I also looked at the biologic plausibility. Does it make sense? What the literature is reporting, does it actually make sense? Is there a mechanism by which this could actually be happening?

Q. Now, were you familiar with the proposed association between the use of talc in the perineal area and ovarian cancer before you began your review

for this lawsuit?
A. I was.
Q. How so?
A. Well, somewhere along my training at various times I know that there have been publications on talc and the risk of developing ovarian cancer. I know that Dr. Cramer published the first case-control study on this back in 1982. I wasn't in medical school in 1982. So I don't think I read that. But I do remember somewhere along in my training -- be it medical school, be it residency, reading some of the literature and having discussions with other learners, with professors about talc and the risk of developing ovarian cancer.
Q. Now, in the course of your career, have there been other hypotheses put forward in the literature regarding environmental agents and an increased risk of ovarian cancer?
A. Yes.
Q. Can you give me some examples?
A. Since ovarian cancer really is such a horrible disease in terms of killing more than half of the women that are diagnosed with it every year, many, many people are trying to identify environmental agents that may actually increase the risk of ovarian

cancer in the hopes of somehow impacting the incidence of this disease.

More recently, there have actually been three articles, if you will, that I actually put into my report that have identified environmental agents, such as television watching, which they have identified and said doubles the risk of developing ovarian cancer, eating processed meats, which increases the risk of developing ovarian cancer by half, and taking Valium, which has been reported to increase the risk of developing ovarian cancer by almost 20 percent.

These are published manuscripts in peer-reviewed literature, but nobody in the gynecologic oncology community really believes that these environmental exposures and reducing these environmental exposures would reduce the incidence of developing ovarian cancer.

Q. Now, the studies -- I just want to be a little bit specific. The studies you cite in your report, for example, for television watching, is the odds ratio there 2.15 with a statistically significant confidence interval?

A. Yes.

Q. And for eating processed meat, is the point estimate 1.49 with a statistically significant

confidence interval?
A. Yes.
Q. And for the use of anxiety medication, like Valium, is the risk ratio 1.17 with a statistically significant confidence interval?
A. Yes.
Q. In your counsel -- do you counsel patients not to watch too much TV or to not eat processed meat or to not take anxiety medication in the hope of reducing their risk of getting ovarian cancer?
A. I may counsel them to do those things, but not in order to reduce their risk of ovarian cancer. For other health reasons I may counsel them to do those things. But reducing television watching, not eating processed meat, not taking too much Valium, I don't believe there is any biologically plausible mechanism by which doing those things would reduce their risk of ovarian cancer.
Q. Now, we're focused in this litigation on epithelial ovarian cancer. Are there different subtypes of epithelial ovarian cancer?
A. There are. And the different subtypes are called the histologies, and the histology is how the cells look under the microscope, or at least that's how we used to limit our discussion.

Now, we actually know that the different histologic subtypes actually have different origins, different molecular pathways by which these different histologies develop. Additionally, they responded to most therapies differently. So it's not just the appearance of the cell; it's also how they come about to be a cancer and the ways that they respond to treatments.

Q. Where do ovarian tumors develop? Do we know this?

A. That's a complex question. It seems that the different histologic subtypes probably originate in different areas. So, for example, the serous subtype, which is the most common histologic subtype, we now think, based on research that has been done in the last 5-to-10 years, that probably 60 to 70 percent of the serous carcinomas actually come from the fallopian tube. But the other 30 percent may actually still originate in the ovary.

Q. Is it more accurate to describe ovarian cancer as a single disease or as a collection of different unique diseases?

A. They are definitely different unique diseases. We know, for example, that the serous carcinomas have a very different chemo response pattern than, say, the

mucinous carcinomas which are notoriously insensitive to chemotherapy.

Q. Do each of those unique cancers, what you called the different histologic subtypes, have different risk factors associated with them?

A. So collectively, there are certain risk factors that seem to apply to all of the different histologic subtypes, but there are definitely certain risk factors which seem to only impact or have influence or be associated with certain subtypes.

Q. What about in terms of treatment; does treatment vary by histologic subtypes?

A. Absolutely. Serous carcinomas are known to be very sensitive to the platinum agents, and the mucinous carcinomas don't seem to actually have any sensitivity or very reduced sensitivity to the platinum agents, and sometimes we actually change the chemotherapy from which we typically give for ovarian cancer to something that you would give for, say, a gastrointestinal cancer because the mucinous ovarian cancers act more like a gastrointestinal cancer.

Q. Let's talk about the risk factors. You mentioned a bunch of them earlier today. What is a risk factor?

A. A risk factor is something that has been

associated with the development of a disease. It is not necessarily a causal agent. For example, if we take age, age isn't causing ovarian cancer, but we know that as a woman ages, her risk of developing ovarian cancer increases.

Q. To the extent an expert were to testify that risk factors for a disease and the causes of a disease are the same thing, would that be correct?

A. No, that's not correct.

Q. How does something become an established risk factor for ovarian cancer?

A. Something becomes an established risk factor by epidemiologic studies being conducted to fully explore the association between the risk factor and the development of the disease. Typically, this would start off with case reports or small series reports where you might collect data on 10 or 20 patients. And then a case-control study would be done in order to determine whether or not there was an odds ratio that was significant.

With that information you might then go on and examine a cohort study to again try and solidify the association between that risk factor and the development of the disease.

Q. Now, you've helped us with a slide, and you've

already mentioned some of these, but I wanted you to note for the Court that some of the established risk factors in the right-hand column listed here have a slightly shaded box, that is the last three, endometriosis, tobacco smoking, and obesity. Why did you ask us to shade that box?

A. I asked you to shade those boxes because those risk factors are not known to be associated with the entity known as epithelial ovarian cancer, but they are histologic-specific.

So, for example, endometriosis is known to be associated with the development of endometrioid and clear cell carcinomas but not high grade serous carcinomas.

Tobacco smoking is known to be associated with the development of mucinous carcinomas but not the other histologic subtypes.

Q. What, if anything, does the fact that there are some risk factors that are specific to certain subtypes of ovarian cancer and not others, what does that tell us generally about the causes of ovarian cancer?

A. So what that tells us and also what we know from examining the molecular profiles of these different histologic subtypes is that these different histologic

subtypes of ovarian cancer are very, very likely to have different underlying causes.

Q. You mentioned genetic mutations earlier as a risk factor. What is the increased risk associated with inherited mutations?

A. So that depends upon what mutation you inherit. The two most common inherited mutations in ovarian cancer are mutations in either BRCA 1 or BRCA 2. The risk of ovarian cancer with BRCA 1 is a bit higher than BRCA 2. With BRCA 1 mutations, increasing the risk of developing ovarian cancer is somewhere in the range of 40 to 53 percent over the course of a woman's lifetime.

Q. As compared to women who do not have that mutation?

A. As compared to women who do not have any known inherited mutations where the risk of developing ovarian cancer is 1.3 percent.

Q. And how about BRCA 2?

A. So if a woman has inherited a mutation in BRCA 2, her risk of developing ovarian cancer is in the range of 22 to 30 percent over the course of her lifetime.

Q. Just to put that in perspective, how would the information you just gave us, which was between

roughly a 20 percent and a 40 percent risk over the course of a woman's lifetime, how would that be stated in terms of a percentage of increased risk? Are we talking in the thousands of percent?

A. Yes, because if somebody has a 1.3 percent risk of developing ovarian cancer, a 100 percent increase in developing ovarian cancer, wouldn't she have a two times risk of the 1.3 percent? So if you take that 40 percent that we talked about, that's actually magnifying that 1.3 by about 4,000.

Q. Now, are all of the genetic mutations that increase the risk for ovarian cancer found in either BRCA 1 or 2? You told us that's not true?

A. That's not true. They are the two most common, and they -- right now in terms of the state of the science, they account for about 70 percent of the known inherited mutations which increase the risk of ovarian cancer.

There is another cluster of genes, if you will, which accounts for another 29 percent of the inherited mutations, and these genes individually don't have a huge amount of responsibility for inherited ovarian cancers, but together they do, and that's about another, right now, 15 to 16 different genes, and then the Lynch syndrome family which

consists of four genes, accounts for about 1 percent of the inherited cancers.

Q. Are there any factors that decrease the likelihood of getting ovarian cancer that reduce the risk?

A. Yes. As I mentioned before, use of oral contraceptives for five years or more, contiguous use, can decrease the risk by about half.

In addition, breast feeding can reduce a woman's risk of developing ovarian cancer.

Tubal ligation can reduce the risk of developing ovarian cancer.

Having many children can reduce the risk of ovarian cancer.

Q. Now, sometimes the factors that you just referred to that decrease a woman's risk of developing ovarian cancer are referred to as protective factors. Have you seen that sometimes in the literature?

A. I have seen that, but I don't really use that word, and I don't like that word being used in that context because even a woman who has had many children, breastfed each and every one of them, and then had a tubal ligation, or even used birth control pills, can still get ovarian cancer.

So those factors may reduce the risk and have

been shown in the epidemiologic literature to reduce the risk, but it is not preventative. The only thing that can prevent ovarian cancer is surgical removing the tubes and ovaries.

Q. Do you prescribe -- strike that.

You mentioned earlier today you sometimes prescribe birth control pills to reduce the risk of ovarian cancer. Is that true?

A. That's correct.

Q. What about NSAIDs or anti-inflammatories?

A. I don't prescribe aspirin or nonaspirin NSAIDs as a method to reduce the risk of ovarian cancer.

Q. Why not?

A. Because the literature on that is very inconsistent. There have been several studies published that show variances such as low dose daily aspirin may reduce the risk, but then use of nonaspirin NSAIDs may actually increase the risk of ovarian cancer.

So since the epidemiologic literature on this is very inconsistent, prescribing NSAIDs as a method to reduce the risk of ovarian cancer is not something that's accepted by the gynecologic oncology community.

Q. One of the issues about which there has been a lot of discussion here over the past two weeks is

whether or not there is some sort of consensus in the gynecologic oncology community that perineal talc use causes ovarian cancer. And yesterday there was a whole back and forth between Ms. Brown and Dr. Clarke-Pearson. I'm not going to go through all the different organizations, but I do want to ask you this:

Is there in your view, based upon all of the work that you have done, a general consensus within the gynecologic oncology community that perineal talc use causes ovarian cancer?

A. No. There is no consensus in the gynecologic oncology community that talc causes ovarian cancer. Our professional organizations do not support that hypothesis.

Q. Now, there has been a lot of testimony regarding the SGO, ACOG, the NCI, which is part of the NIH, Center for Disease Control, the FDA, IARC and multiple different studies that have been done.

My question to you is: Do any of the health organizations that I just mentioned assert that the data supports a causal association between talc and ovarian cancer?

A. No, none of them do.

Q. Good. I want to be a little bit more specific

about one of those agencies, the National Cancer Institute or NCI.

Yesterday Dr. Clarke-Pearson was critical of the NCI PDQ.

MR. WILLIAMS: If we could bring that up, that's Exhibit A 104.

(Pause.)

Q. If we could turn to page 13 of A 104.

Dr. Saenz, you are familiar with this description of factors with inadequate evidence of an association?

A. I am.

Q. I want to direct your attention to the perineal talc exposure paragraph at the bottom of this page which says:

"The weight of the evidence does not support an association between perineal talc exposure and an increased risk of ovarian cancer."

And then it goes on a little bit later to have some citations there, and later on, on the next page.

Yesterday there was some discussion with Dr. Clarke-Pearson that the studies here were old studies, that it was not up to date.

First of all, did you listen to Dr. Clarke-Pearson's testimony from the other room?

A. I did.
Q. Did you listen to all of it?
A. I did, except when I had to go to the bathroom.
Q. Do you agree with the National Cancer Institute that the evidence concerning talc and ovarian cancer is inadequate to establish a causal connection?
A. I agree with the NCI that the literature is inadequate, that there is no demonstration in the literature of a causal role of the perineal application of talc and the development of ovarian cancer.
Q. If we could turn to page 18.

There was discussion yesterday concerning this portion of the PDQ, and specifically the portion that talks about the purpose of the summary and the reviewers and updates.

Have you reviewed this document?
A. Yes, I have.
Q. You see there and, in particular, the portion under "Reviewers and Updates" there was some discussion yesterday, Doctor, with Dr. Clarke-Pearson when Ms. Brown was cross-examining him that talked about this portion that refers to the methodology that is used by the editorial board of the NCI.

Do you recall hearing that?

A. I do.
Q. It refers here in the first sentence under "Reviewers and Updates," it says:
"This summary is reviewed regularly and updated as necessary by the PDQ Screening and Prevention Editorial Board, which is editorially independent of the NCI."
And it goes on to discuss their meetings and how often they discuss things.
Have you looked at that link there to the PDQ Screening and Prevention Editorial Board?
A. I have not actually looked at that link. I have seen this page, but I haven't clicked on that link.
Q. Let me show you what I'll represent to you what appears when one clicks on that list, and it just gives a list of the members of the editorial board.
MR. DEARING: Your Honor, I object to this. This is a demonstration where the witness said she doesn't have any knowledge about this. It's improper. It's not in her report, and it wasn't in her deposition.
MR. WILLIAMS: The reference to this document is in her report, the NCI website, your Honor.
THE COURT: I want to see where the question goes. I don't know if we're going to get more

specific. I think he's just going to show us what's on the page.

MR. WILLIAMS: I'm just going to show her.

THE COURT: That's what I had a feeling it was going to be. If there is no more information on it, who the Board members are -- is that what you are representing?

MR. WILLIAMS: That's all.

THE COURT: I had a feeling that's what was coming. So with that basic representation.

BY MR. WILLIAMS:

Q. Dr. Saenz, I realize that you have not -- you have testified, rather, that you have not personally reviewed this document or gone to this link on the website.

First, let's take a look at those two pages. Does that purport to be a listing of the Screening and Prevention Editorial Board members?

A. Yes, it does.

Q. Just browsing through that quickly, do you recognize the medical centers and organizations with which the members of that board are affiliated?

A. Yes, I do.

Q. Is it fair to say that the organizations and universities with which those individuals are

associated are among the best medical organizations in the country?

A. They give a fair representation of excellent cancer centers across the country, yes.

Q. Very good. Let's switch topics.

THE COURT: While you are switching topics, I want to ask a question of the Doctor.

When did you become involved in these litigations?

THE WITNESS: I was first contacted by counsel in November of 2016.

BY MR. WILLIAMS:

Q. Let's switch gears and discuss the concept of biologic plausibility.

Dr. Saenz, what does that concept of biologic plausibility mean to you?

A. So to me biologic plausibility means that you are proposing a hypothesis, and based on that hypothesis, the concept that whatever it is you are proposing could actually happen is substantiated by some science that has been done in the field.

Q. Now, does the science in your view for biologic plausibility need to be proof positive?

A. No, it does not need to be proof positive for there to be biologic plausibility, nor does it need to

be an exact representation of whatever is your hypothesis. It can just be that there is enough science to make sense and extend it.

So, for example, if I may, we know that smoking causes lung cancer. In terms of evaluating whether or not secondhand smoke can cause lung cancer, you don't have to go through the process of repeating everything that you did for secondhand smoke that you did with smoking for you to get that it's biologically plausible that secondhand smoke causes cancer.

Q. Do you believe there needs to be some sort of scientific data that moves us from hypothesis into the realm of a cohesive theory supported by the science that has been done?

A. Absolutely. You can't just say I'm going to come up with a hypothesis and not have any proof whatsoever, not have any documentation of mechanism of some sort that substantiates that hypothesis in order to say there is biologic plausibility. That's just guessing.

Q. For example, in this case in the last two weeks there has been discussion about whether scientific data indicates that talc can cause inflammation. You are aware of that. Right?

A. Yes.

Q. There has been some discussion of the idea that talc -- excuse me -- that inflammation is associated with certain types of cancer. You are aware of that?
A. Yes.
Q. Here, based and upon your review, is there data indicating that with some weight that ovarian cancer, in particular, is associated with inflammation?
A. So, the hypothesis that has been put forth in this case is that chronic inflammation leads to the development of ovarian cancer, and the weight of the literature that has been published does not support that hypothesis.

That means there is not a biologically plausible explanation for how chronic inflammation could cause ovarian cancer.

Q. We'll talk a little more about inflammation a little later. Let me ask you now about the topic of migration.

MR. WILLIAMS: And if we could go to slide 5.

Q. Plaintiffs' experts claim that talc migrates from the perineum to the ovaries. Based upon your medical training and experience and your review of the scientific literature, do you agree with that?
A. I do not agree with that.
Q. Can you walk us through the pathway of the

female reproductive track where talc particles would have to traverse to get to the ovaries?

A. So when talcum powder is applied to the genitalia, it's applied out here on the labia majora, which are a rather large outer organ. It's the skin surface. And the labia majora are opposed meaning they are touching each other. They are naturally closing off entrance into the inner anatomy.

Once you get past the labia majora, you encounter the labia minora, which are the inner labia, and these as well, are opposed, which means they are closed off.

Beyond that you have to get over the perineal body, which is a muscle to get entry into the vestibule and the vagina. The vagina is naturally collapsed. It's not wide open. It's why we have to use speculums when we are doing pelvic exams, because you can't just separate the labia and see into the vagina.

The vagina itself is naturally about 7 to 8 centimeters long, sometimes a little bit longer, but it's about as long as my finger, and that entire area would need to be traversed to get to the cervix.

The cervix is another 3 to 4 centimeters, and it is filled with mucus.

The uterus itself has an endometrial cavity, which it, too, is collapsed and the anterior surface opposes the posterior surface. The entry into the fallopian tubes is way up at the top of the uterus, and that's a small opening that then leads to the fallopian tubes.

So there is, No. 1, no literature that has ever shown any particulate matter migrating from the outer labia majora to the perineum all the way to the ovaries. There are studies that show placing particles way up here in the posterior vagina that those particles can end up being found in the fallopian tubes. But placing something up here in the posterior vagina is not the same as applying powder out here.

Q. To the extent an expert were to testify that the vagina is open to the outside world, would that be accurate?

A. That is not an accurate description. It's not reality. Otherwise, why would we need to place a speculum into the vagina in order to see the vaginal walls and see the cervix? It is not wide open. It's not an open cavity. It's closed. It's collapsed, and the labia are covering it.

Q. Is there data from the epidemiologic studies

that you have reviewed that informs your opinion on whether it matters if talc could migrate all the way to the ovary?

A. No, it doesn't really matter because even if talc was migrating all the way from the perineum to the ovary, there is still no evidence that chronic inflammation is the cause of ovarian cancer. There is no biologically plausible mechanism by which that would be causing ovarian cancer.

Q. Let me ask you about some of the literature. One study there has been some discussion about, the Heller 1996 study, which is Exhibit A 60 in your binder -- and let me grab that pointer from you.

You reviewed this study, Doctor, haven't you?

A. Yes.

Q. If we could direct your attention to the top of the study.

Is this the study that there was an analysis of 24 women, some of whom reported they used talc and some of them did not?

A. Correct. There were 24 women in this study, 12 of whom reported that they had applied talc to their perineum and the other 12 reported that they had never used talc in the perineum.

Q. Why does it matter that there was talc that was

found in more of the women who reported that they had not used talc in the perineal area than the women who had?

A. Well, in this study the talc was actually found in the women that reported no perineal application. So what it says is that the talc got to those ovaries somehow other than perineal application. So it's the perineal application itself does not account for finding talc in the ovaries.

Q. Do we know from the review of the Heller study whether the talc in the ovaries got there before or after the tissue was removed from the body?

A. We do not know that.

Q. How, if at all, does your opinion about whether talc can cause ovarian cancer change if talc could migrate to the ovary?

A. It doesn't change my opinion because we still don't have any biologically plausible mechanism by which talc being in the ovaries would then be causing ovarian cancer.

Q. Have you reviewed studies, epidemiological studies, that have analyzed associations related to the introduction of talc into the vaginal area by means of condoms or diaphragms?

A. Yes.

Q. Are those studies listed in your report?
A. Yes.
Q. Let's take a look at Cramer 2016, which is Exhibit A 25. Let's look at Table 1 on page 4.
There is a table on page 4 entitled "Type, Timing and Duration of Genital Talc Use."
Do you see that?
A. Yes, I do.
Q. What was the finding here with respect to potential exposure in women with no personal use but diaphragm only use?
A. These are women who placed talc on their diaphragms, and what Cramer found in his manuscript published in 2016 is that these women actually had a protective effect against the development of ovarian cancer in the range of about 27 percent because the odds ratio for women who dusted their diaphragms with talc was 0.73 with a significant confidence interval.
Q. Let me stop you there on the confidence interval. You see this confidence interval crosses the baseline of 1. Does that tell you this is not a statistically significant finding?
A. Actually, Mr. Williams, it does not.
Q. Excuse me. I misspoke. This particular confidence interval.

THE COURT: The next one does.

MR. WILLIAMS: Yes, I beg your pardon.

Q. For the diaphragm only use, this specific confidence interval does not cross 1. What is the significance of that?

A. That means it's a statistically significant finding, but I don't believe this -- I don't believe that dusting your diaphragm with talc would help prevent ovarian cancer. I'm not going to now go tell patients that, and the reason for that is the same thing. There is a lack of biologically plausible mechanism by which dusting your diaphragm with talc would protect you against ovarian cancer.

Q. What, if anything, does this statistically significant finding for the introduction of a diaphragm with talc on it, what does it do for you in terms of your analysis of the consistency of the literature on the ultimate question here?

A. So earlier I commented on how, when I read all of these studies I look for inconsistencies, even within an individual study, and to me this is a perfect example of that. Conceptually it makes no sense that putting talc on your diaphragm, which then goes in and sits at the mouth of your cervix, would reduce your risk of ovarian cancer; whereas, placing

talc outside on the perineum, a good 7, 8 centimeters away would increase your risk of ovarian cancer. That's where I think the studies conflict within themselves, and that's part and parcel of the reason that I do not believe that the literature supports a causal role of talc in the development of ovarian cancer.

Q. Now, the next line, when I prematurely went to it, that is not statistically significant relates to condoms with or without diaphragm. Is that correct?

A. Right. And so condoms could theoretically be dragging talc particles into the vagina or condoms may actually be dusted with the talc, and, again, the odds ratio is less than 1, showing potentially a protective effect, although, as you stated, that confidence interval is not significant because it crosses 1.

Q. Let's look at one more study really quickly on this topic. It's a study about which we had much discussion. It's the Penninkilampi 2018 study, Exhibit A 109.

Did that study as well look at the question of diaphragm use?

A. Yes.

Q. I'll direct your attention to page 5 of Penninkilampi, Table 1, entitled "Method of Talc Use."

First of all, Doctor, can you tell by looking at this chart how many studies were combined in the Penninkilampi meta-analysis related to talc dusted diaphragm use?

A. So from this meta-analysis, they were able to identify eight of the studies that reported on diaphragm use -- on talc being applied to the diaphragm.

Q. Does Table 1 have an odds ratio for diaphragm use?

A. Yes, it does. It has an odds ratio of 0.84, which again, being less than 1 would suggest a protective effect; but like we've talked about before, this is not a statistically significant finding because the confidence interval overlaps 1.

Q. Now, had the .84 odds ratio been statistically significant, what kind of effect or association would that have shown from the use of talc in diaphragms?

A. Again, that would suggest a protective effect from dusting your diaphragm with talc and then inserting it at the mouth of the cervix.

Q. Now, Table 1 also reports just below on sanitary napkins with 12 studies being reviewed. Is that right?

A. That's correct.

Q. How did this result, both individually and collectively with what we saw in Cramer 2016, inform your opinion in this case that the data and the literature supports a finding that perineal use of talcum powder does not cause ovarian cancer?

A. So, again, I find this conflict, if you will, between putting talc on a diaphragm and placing it at the mouth of the cervix creating a protective effect just inconsistent and confusing in terms of why would that be protective; but then placing it on a sanitary napkin outside on your vulva increase your risk of developing ovarian cancer. It doesn't make sense that you are placing a talcum powder product even further away from the ovary when you put it on the sanitary napkin and increasing the risk, but when you place it at the cervix on the diaphragm, you are decreasing the risk.

Q. New topic. I want to ask you about your clinical experience treating patients who have ovarian cancer.

How many patients with ovarian cancer have you operated on in the course of your career, roughly?

A. Again, it's most of the patients that I care for, I've usually operated on; some patients granted transfer care after they had surgery, but I would say

it's somewhere between 1500 to 1800.
Q. Have you ever seen evidence of an inflammatory process during any of those procedures?
A. So during the procedure, the cancer itself is already developed and can be inflammatory. But when we look at the microscope slides, which we do with the pathologist during a treatment planning conference, which we have twice a month, we don't see evidence of foreign body granulomas, evidence of a chronic inflammatory response that would have been incited by a foreign body.
Q. Is part of your practice to review the pathology slides for the women upon whom you have operated?
A. I look at the pathology slides on every patient upon which I perform surgery.
Q. In your over 20 years of practicing as a gynecologic oncologist, have you ever seen evidence of the inflammatory processes that you have mentioned -- granulomas, for example, foreign body giant cells? Have you ever seen that type of evidence in your ovarian cancer patients?
A. I've seen it if somebody had prior surgery, and there was old suture material there, or if there were staples that were there, the body has essentially mounted an immune response to that foreign body. But

irrespective of that, I have not seen it.
Q. In addition to operating on patients who have already been diagnosed with ovarian cancer, you've told us that you do preventative work as well. Is that right?
A. That's correct. I do surgery to remove the tubes and ovaries of women prior to them being diagnosed with ovarian cancer.
Q. Let me ask you about that subset of patients with whom you have associated.
Those surgeries are conducted on your patients who are at high risk for developing ovarian cancer?
A. Correct.
Q. How many surgeries of that type have you performed in your career?
A. I never tallied them, but I do two to three a month of that type of surgery. So you could do the math, but I can't right now.
Q. You were asked about and testified in your deposition about precursor lesions. What are those?
A. So for the women that have BRCA 1 and 2 lesions, we know that those women are at an increased risk of developing serous carcinomas. Recently -- and by that I mean in the last five to eight years -- we have become more sophisticated about being able to identify

changes in the cells in the fallopian tubes which appear to be precursor lesions to the women that are at risk for developing ovarian cancer.

And so in any patients that I'm doing surgery prophylactically in order to reduce her risk of cancer, those tissues, the ovaries and the tubes undergo this special staining process in order to look for those precursor lesions.

Q. With respect to those precursor lesions, if those lesions were not removed, is the scientific understanding that they would have progressed to cancer?

A. Yes. So there is actually an acronym for those lesions. They are called STICs, which stands for "serous tubal intra-epithelial carcinoma," meaning that the cancer is beginning to develop but it's not yet invasive.

Within those STIC lesions we can also stain for a mutation in the p53 gene.

THE COURT: You were using stain?

THE WITNESS: Stain.

Q. Go ahead.

A. It's an antibody that is actually tagged with like a dye, if you will, so that the cells that have the p53 mutation look a different color than the cells

that do not have the p53 mutation.

Q. Is it your practice to review the pathology for these patients as well?

A. Yes.

Q. Have you seen any evidence of inflammation in these patients with the STIC lesion?

A. No.

So I've looked at these specimens, if you will, the tubes and ovaries of these high risk patients. I've looked at the tissues that have been stained to identify cells that contain p53 mutations and cells that have STIC lesions or tubes that have STIC lesions, and there is no associated inflammation with these tissues, even though the cancer is already in the process of developing.

Q. Let me ask you about pelvic inflammatory disease, PID. There has been testimony about that. Does PID cause adhesions?

A. PID can definitely cause adhesions.

Q. What are adhesions?

A. Adhesions are essentially scar tissue. They are mainly composed of fibrin, which is a type of tissue that's fibrous, like you would find in a piece of meat. They can be thick. They can be filmy. They are essentially leftovers from an inflammatory

process.
Q. Have you reviewed the literature on PID and ovarian cancer?
A. I have.
Q. Dr. Clarke-Pearson testified yesterday that PID causes ovarian cancer. Did you hear that testimony?
A. I did.
Q. Does the literature support that conclusion?
A. No. The literature on PID and its relationship to ovarian cancer is actually fairly inconsistent. PID in and of itself has not been the associated with the development of ovarian cancer unless patients have reported having more than one episode, and then the type of ovarian cancer is not invasive epithelial ovarian cancer; it's something called a borderline tumor, and borderline tumors are a distinct entity from the types of cancers we have been talking about here.
Q. Does the data show that rates of ovarian cancer, cancer risk increase in women with known inflammatory conditions?
A. No. In fact, it doesn't. We know women, for example, with ulcerative colitis or Crohn's disease, but these women are not at an increased risk for developing colon cancer, and they are inflammatory

conditions, but these women are not at an increased risk for developing ovarian cancer.

Q. Is one of the cases you've reviewed, the Merritt 2008 study?

A. That's one of the case-control studies I've reviewed, yes.

Q. Let's take a look at P 502. There has been testimony about it. Can we look at page 2. I just wanted to point out -- actually, page 3.

Who does this indicate was the sponsor of this research?

A. The U.S. Army Medical Research and Materiel Command.

Q. Let's look at page 3 of the document in the second sentence of the second full paragraph. The author states -- the first full paragraph:

"The aim of the current study was to further examine the role of local chronic inflammation in the development of epithelial ovarian cancer overall by histologic subtype."

Was that the purpose as you understood it?

A. Overall and histologic subtype, yes.

Q. Let's look at page 5 of Exhibit P 502, Table 3.

What do the authors of the Merritt study conclude about whether chronic inflammation causes

ovarian cancer?

A. So the authors of this study, based on actually trying to examine other inflammatory conditions such as PID, mumps or even endometriosis, concluded that inflammation is not a reasonable hypothesis for the development of ovarian cancer.

Q. Let's look at page 7 at the end in the conclusion. It's on page 7. Just above the acknowledgements in the paragraph on the right-hand column, this says:

"However, experimental evidence that perineal talc use elicits an inflammatory response in the ovaries is lacking, and, overall, we conclude that chronic inflammation does not play a major role in the development of ovarian cancer."

Is that conclusion consistent with the review of literature that you have done?

A. Yes, it is.

Q. Let me ask you about CA-125. We've heard testimony that's a protein that is ubiquitous on epithelial cells. What kinds of things elevate CA-125 levels?

A. Many things elevate a C-125 level. It's why it is not a good screening test for ovarian cancer. Pregnancy can elevate a CA-125 level; pelvic

inflammatory disease can elevate it; fibroids can elevate it; pregnancy can elevate it.

Q. Now, Dr. Saed's experiment, one of the experiments that he did, purported to find cells treated with talc produce increased levels of CA-125.

My question is: Is an increase in CA-125 evidence of malignant transformation?

A. No.

Q. What, if anything, does an increased level of CA-125 tell us about whether talc causes ovarian cancer?

A. It doesn't tell us anything about whether talc causes ovarian cancer because CA-125 is just a protein that is being shed and can be shed for many, many reasons. It doesn't elevate as part of the neoplastic transformation. It's a response marker. It's not initiating the cancer.

Q. Last topic. We're not going to do an exhaustive review of all the epidemiological studies.

THE COURT: Excuse me. Explain what you mean by "It's a response marker."

THE WITNESS: So in ovarian cancer, the CA-125 will elevate in about half of the women that have ovarian cancer when it's just Stage I or Stage II. But most women that it's found to be elevated in, it

doesn't elevate until the disease is already Stage III or Stage IV.

So it's not even an early marker for ovarian cancer. It's not there yet. So it's not elevated even when the cancer is initiating in over half of the women. It's only elevating after the cancer has already developed.

THE COURT: Now, you reviewed Dr. Saed's expert report?

THE WITNESS: I did.

THE COURT: Did you review his publication?

THE WITNESS: I had not, your Honor, by the time of my deposition, but I have since read his manuscript, okay.

THE COURT: Essentially, his report and the manuscript are very similar and the findings that they make.

THE WITNESS: I think the only major discrepancy I found was that he reported in his report for this matter that he treated the cells for 72 hours, but then in his manuscript he changed that to 48 hours.

THE COURT: I think it's the reverse. The report said 48 and the manuscript said 72. That was changed at some other point. Put that aside.

Did you critique in your report Dr. Saed's findings?

THE WITNESS: Not on his experiments, your Honor. I really deferred that to Dr. Neel and some of the other cancer biologists involved in this matter.

THE COURT: But as to his findings.

THE WITNESS: I didn't put it in my report, but I'll be happy to answer any questions now.

THE COURT: It's not part of what you have in your report. Okay.

I think there were some parts of it in her deposition testimony that she reacted to.

THE WITNESS: I did get asked questions in my deposition.

MR. WILLIAMS: I think there is some reference in her report as to Dr. Saed's analysis.

THE COURT: There is some, but I don't know how complete it is.

THE WITNESS: If I may, your Honor, in my report I did comment on his abstract about the CA-125 levels, but I did not comment on the generation of reactive oxygen species.

THE COURT: Got it. So we won't go there.

MR. WILLIAMS: The CA-125 reference is on page 31 of Dr. Saenz's report.

THE COURT: That I saw in there and that's as far as it went.

Thank you.

BY MR. WILLIAMS:

Q. So the last topic I wanted to focus in on is the cohort studies, and, in particular, some of the testimony that we've heard over the last two weeks on the Nurses' Health Study, Penninkilampi and Berge. I would like to focus on that.

Are you familiar with the Nurses' Health Study?

A. Yes, I am.

Q. How old were the women at the time of enrollment?

MR. WILLIAMS: And if we could pull up slide No. 6.

Q. Did you help us prepare this summary in the Nurses' Health study?

A. I did.

Q. How old were the women at the time of enrollment?

A. So at the time of enrollment in 1976 the women spanned the ages of 30 to 55.

Q. In connection with forming your opinions in the case, did you review Gertig 2000, Gates 2008 and Gates

2010?
A. Yes, I did.
Q. Let's focus on Gertig 2000 first.
Did the Nurses' Health Study obtain information about perineal exposure to talc from participants?
A. Yes, it did, although the initial study started in 1976. In 1982 the study authors sent questionnaires that included questions about the frequency with which women were applying talc to the genital area.
Q. How many women formed the cohort for analysis?
A. It was almost 79,000 women.
Q. How long were the women studied?
A. So the women in this study, this initial Gertig 2000 study, were followed for 14 years.
Q. Please take a look at Table II on page 3 of Exhibit A 45. We'll have it on the slide.
What were the results of Gertig 2000 for ever never perineal talc use for all subtypes combined?
A. So Gertig 2000 reported nonstatistically significant relative risk for ever use of talc in terms of increasing the risk of developing ovarian cancer with a value of 1.09, and a nonstatistically significant confidence interval of 0.86 through 1.37.

Q. Now, in Gertig 2000 the authors also analyzed the findings for serous ovarian cancer specifically. Right?
A. Yes, they did.
Q. If we look down at the bottom on Table 3 on that page, page 4, I believe, of the exhibit, what was the finding?
A. So Gertig 2000 reported for the serous histology only a statistically significant risk factor of 1.40 with a confidence interval that was significant at 1.02 through 1.91.
Q. Now, did that statistically significant positive association fall away with Gates 2010?
A. It fell away not only with Gates 2010 but also with Gates 2008.
Q. Let's focus on 2010 first, and this is Exhibit A 42. We prepared a slide for this one as well.
Is Gates 2010 another cohort looking at data from the Nurses' Health Study?
A. I wouldn't say it's another cohort. I would say it's an extension of the original cohort. Essentially 10 more years of time elapsed. During that time, the authors collected data, again, on how many more women were developing epithelial ovarian cancer. So in 2000, I believe there were 307 cases. By 2010, so,

now a full 24 years of follow-up on this cohort, there were an additional almost 600 more cases. It went from 307, I believe, to 876 women diagnosed with epithelial ovarian cancer.

Q. Let me stop you there. You indicated earlier that 1982 was when women were first asked about their use of talcum powder. Correct?

A. Correct.

Q. Should we assume -- and did you assume in your analysis that those women started using talc on the date in 1982 when they filled out the form?

A. No, not at all, because we know from Cramer 2016 as well as from IARC that reported that most women that used perineal talc actually usually start in their twenties. And so the women in the Gertig study in 1982, when they were first asked about their use of talc, were well beyond that age. So I did make an assumption but based off of the literature on this topic, that those women were already habitual users if they were users.

Q. Looking at Table 4 of page 8 on Exhibit 842, what were the talc use categories in Gates 2010?

A. So in Gates 2010, they did a comparison not of ever never users, but they did it of women that used talc greater than one times per week versus women that

used it less than one time per week, which also includes the never users.

Q. And were the results of Gates 2010 -- the Court heard this before -- that there was not a statistically significant association for any subgroup of ovarian cancer or overall?

A. Correct.

Q. Now, let's go to the next slide.

Dr. McTiernan told the Court that because Gertig looked at ever/never use, whereas Gates 2010 looked at that different metric, meaning greater than once per week versus less than once per week, that you just testified about, that the risk in Gates 2010 was, in her words, attenuated.

Let me ask you this: "Attenuated" in this context would mean that taking out the women who used less than once per week and putting them in the infrequent user category that you mentioned would decrease the risk ratio for the user category. That's what Dr. McTiernan was saying, right?

A. She's saying that by removing the women that used it less than once per week from the women that used it more often decreased that relative risk number, she's making that assumption. Correct?

Q. Is Dr. McTiernan's testimony supported by the

studies upon which you and she relied?
A. No.
Q. Why not?
A. Actually, it's the opposite of what she assumed and asserted. What Gates 2010 did was focus on the habitual users. They did not want the risk, if there was one, that would be associated with the habitual users to be diluted, if you will, by the infrequent users.

So they pulled the women out that were using talc less than once per week and grouped them with the never users. The intent of this was to in fact magnify the risk of habitual users if in fact there was a risk.

Q. Let's take a look at Gates 2008 to see what you are saying.

Did Gates 2008 report on the same cohort of women from the Nurses' Health Study that we saw in Gertig 2000?
A. Yes, they did.
Q. Let's look at Gates 2008, Table 3. This is Exhibit A 43.

What were the results in Gates 2008 in the category of women that used talc less than once per week? Was the result above 1.0 or below?

A. So in Gates 2008, what the authors found was that the women that used talc less than 1 time per week had a relative risk of 0.98, which meant their risk was actually even lower than the women that were never users.

So this is exactly what I was talking about before. By grouping the never users with the less than one time per week women -- you are pulling out the infrequent users from your more frequent users so that you could in fact magnify an effect if there was actually one there.

Q. Using this table, can you explain to the Court why the data from this study does not support Dr. McTiernan's assumption about attenuation?

A. Dr. McTiernan is making the assumption that any exposure to talc will increase your risk of ovarian cancer. What this data shows is, actually, that if you use talc less than one time per week, your risk is no different than a never user.

So had these women that used less than one time per week been left in the classification with the users that used it one to six times per week, or more often, the reported relative risk would have actually been lower than what was reported in the 2010 publication, not higher like what was suggested by

Dr. McTiernan.

Q. And was that true for the serous subtype as well?

A. That was true for the serous subtype as well. In fact, the -- quote, unquote -- protective effect -- because, again, I don't believe that's really protective, but the relative risk for the women that used talc less than one time per week of developing ovarian cancer was only 0.79. So the magnitude of reduction was even greater in the women with serous ovarian cancer.

Q. Now, is this grouping of infrequent users with the never users unique to Gates 2010?

A. No. That attempt, if you will, with the study to focus on grouping infrequent users with the never users and trying to really only focus on the habitual users was also done in a few of the case-control studies, specifically in Schildkraut 2016, and I believe in Wu 2015. Both of those study authors did similar groupings of infrequent users along with the never users.

Q. And you are familiar with the Penninkilampi study?

A. I've am.

Q. Were both Wu 2015 and Schildkraut 2016 with that

different sort of category usage analyzed by the Penninkilampi authors?

A. They were. Basically looking at what's called -- quote, unquote -- ever users versus never users, but they really weren't never users. It was more never/infrequent users in both Wu 2015 and Cramer 2016.

Q. Her Honor asked the question yesterday about the differences between the Penninkilampi study and the Berge study. Did the Penninkilampi study even consider the study that we've just gone through in Gates 2010?

A. No. Penninkilampi did not include that cohort study at all, and I don't really understand that. Gertig had 14 years of follow-up. Gates 2010 had 24 years of follow-up. I don't know why you wouldn't want to report data on a more mature study that collected more cases. The authors never explained it.

Q. Were there other differences with respect to the underlying studies used and analyzed by Penninkilampi and Berge?

A. So with respect to the case-control studies, Berge did not report -- or, I should say, Berge did not include case-control studies, that the data from that study had been subsumed into a later publication,

but Penninkilampi did.

So, for example, Purdie, which was published in 1995, those cases were actually subsumed into Green 1997, and Penninkilampi included both of those studies in their analysis. Berge only included the Green study because that was the later publication.

Q. And so we see here on the slide that's on the board there is a reference here to Purdie 1995. Do you see that, and Green 1997?

A. Yes.

Q. And the slide on the board is summarizing a chart from the Penninkilampi study?

A. Yes.

Q. Finally, Berge -- we've gone through this before. Let's take a look at Table II on page 7 of that study.

What did the Berge study find with respect to whether there was a positive association between perineal talc use and ovarian cancer in the cohort study?

A. So Berge found in the cohort studies that the perineal application of talc did not increase the risk of developing ovarian cancer. This was utilizing all three of the cohort studies and specifically not utilizing the Gertig study but using the more mature

study in the Gates 2010 study.

Q. Over the past few days there has been a fair amount of discussion on the subject of power as it relates to case control and cohort studies.

What did the Berge 2018 authors conclude with respect to the power of the cohort studies?

A. So in an attempt to try to understand I think perhaps why there was a difference in the odds ratios with the case-control studies versus the cohort studies, the authors did a power analysis on the meta-analysis of just the three cohort studies, and they found that by grouping those three studies together, the cohort studies were actually sufficiently powered to detect a relative risk of at least 1.25 if one actually existed, and this was to a certainty of 0.99, which meant there is a less than 1 percent chance that the grouping of the cohort studies together would not be capable of finding that relative risk, but it means that there is a 99 percent chance that these studies are actually powered to detect that relative risk if it exists.

So the authors concluded that you can't simply say that the power of the cohort studies is too low to find that that's not the reason that the cohort studies are not finding a statistically significant

increased risk.

Q. To summarize that finding in Berge, the cohort studies had a 1.02 relative risk. Is that right?

A. That's correct.

Q. Dr. Carson testified that because the cohorts were not able to find a statistically significant association, that they must not have been well powered.

My question to you is: Does that comport with your understanding of the scientific method?

A. That's not how it works.

Q. Why not?

A. Because that would mean that any time you don't have a positive finding, you are just saying the study has no power. That's not how it works.

Q. Is that sort of like saying heads I win, tails you lose?

A. It's kind of saying I'm going to have a positive result; and if I don't get it, then I'm not getting it because the study is not good. That's cherry-picking your results.

Q. Now there has been testimony about clearance from the ovary. Simple question: If something gets to the ovary, for example, a talc particle or bacteria, can it exit?

MR. DEARING: Objection. There is no evidence in the report, no statements in the report about clearance from the ovary.

MR. WILLIAMS: I believe she's qualified. She didn't know people were going to make that statement here, your Honor.

THE COURT: I know. But I am limiting everyone to the opinions they have already given.

MR. WILLIAMS: Very well.

BY MR. WILLIAMS:

Q. Then my last question is: Could you, Doctor, summarize your conclusions regarding whether the literature supports a causal finding that talc causes ovarian cancer with particular attention to the consistency factor that you mentioned at the top?

A. So in my opinion the literature on whether or not perineal application of talc is associated or causes ovarian cancer is that the literature is inconsistent. There are several case-control studies that have been performed which do show an elevated odds ratio in the range of 1.2 to 1.4. But there are also multiple case-control studies that do not show a statistically significant difference; and the analysis of the cohort studies does not support, it's not consistent, with the findings within the case-control

studies.

So I do not believe that the perineal application of talc causes ovarian cancer.

MR. WILLIAMS: No further questions, your Honor.

THE COURT: Thanks.

We'll take our break now.

THE DEPUTY CLERK: All rise.

(Recess.)

(Continued on the next page.)

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THE DEPUTY CLERK: All rise.

THE COURT: Thank you.

CHERYL C. SAENZ, resumed.

CROSS-EXAMINATION

BY MR. DEARING:

Q. Good morning.

Dr. Saenz, you don't have any degrees in epidemiology, do you?

A. No, I do not.

Q. You are not formally trained in epidemiology, are you?

A. I don't believe that's entirely true because, as a composite part of my fellowship training in gynecologic oncology, I do need to know the epidemiology literature, and I do actually publish in epidemiology on gynecologic cancers.

Q. Did you hear my question? My question was: You don't have any formal training in epidemiology. Correct?

A. And I disagree with that, sir.

MR. DEARING: Your Honor, permission to read from her deposition?

THE COURT: Yes.

Q. Page 129, line 12.

MR. WILLIAMS: Your Honor, we would object. It is not proper impeachment. The questions are different and, therefore, the answers are different.

THE COURT: That is a different question. Perhaps you have the wrong cite.

MR. DEARING: I may.

THE COURT: Okay.

BY MR. DEARING:

Q. Do you hold yourself out as an epidemiologist?

A. I do not.

Q. Is it true you are not formally trained in epidemiology?

A. I do have training in epidemiology as it pertains to the GYN field.

THE COURT: Keep your voice up. You were doing great this morning.

Q. You are not a toxicologist, are you?

A. No, sir.

Q. And you don't have any formal training in cancer biology?

A. I don't exactly agree with that. I actually have worked as a WRHR scholar for 4 1/2 years in a cancer biology laboratory, and I published in cancer biology.

Q. You don't hold yourself out as a cancer biologist, do you?
A. That's correct.
Q. And you've never published any research on the issue of talc and ovarian cancer. Is that right?
A. That's correct.
Q. And you have not conducted any experiments on talc and its effect on cells?
A. That's correct.
Q. And you have no opinions whether Johnson & Johnson's Baby Powder or Johnson & Johnson's Shower To Shower products contain asbestos. Right?
A. I am not giving you my opinions today, sir, based on what the constituents are of the product. That's correct.
Q. And you are not an expert on asbestos, are you?
A. That's correct.
Q. And you have no opinion whether asbestos exposure can cause ovarian cancer. Right?
A. No, that's not entirely true. I do know that IARC has published and stated that with heavy occupational exposure there is an increased risk of developing ovarian cancer.
Q. And you don't intend to offer any opinions about the components of the Johnson & Johnson talc products.

I just mentioned their chemical compositions.
A. I do not.
Q. You don't have any opinions about whether Johnson & Johnson's talc contains carcinogenic heavy metals or carcinogenic fragrance chemicals. Right?
A. I will not be giving opinions on the constituents, products or components of Johnson & Johnson Baby Powder.
Q. And you have no opinion whether Johnson & Johnson talc products contain asbestiform fibrous talc. Right?
A. That's correct.
Q. And you have no opinions whether fibrous talc is an established carcinogen. Right?
A. So I do know that IARC has published on fibrous talc I believe in the asbestos monograph and grouped it there, but beyond that I have no opinions.
Q. Are you aware that IARC has grouped fibrous talc as a 1-A carcinogen, that's a known human carcinogen. Right?
MR. WILLIAMS: Objection. Assumes facts and misstates what IARC does.
MR. DEARING: I'm trying to clarify what she just said, your Honor.
THE COURT: She's suggesting that's not

exactly the finding of IARC. If you want to direct her to something, why don't you direct her to the document and what you are relying on.

MR. DEARING: I will come back to the document. I'll lay a foundation for where we are going to go today.

THE COURT: Okay.

BY MR. DEARING:

Q. Let me ask you some questions about migration.

First of all, I put up two anatomy boards here. First of all, where did you get the anatomy slide image you talked about earlier today? Where did that come from?

A. Counsel.

Q. Do you know whether it came from a textbook or a Google search?

A. I actually helped develop that slide with counsel with a medical artist.

Q. So that image isn't published anywhere. That's an image you created?

A. Yes, based on what I think about female anatomy.

Q. Here are two other images of the female reproductive tract. I just want to ask you some questions about it.

Is it true that one of the foundational

building blocks of your causation opinion is that talc and whatever is in talc cannot migrate from the perineum to the ovaries? Is that sort of the foundational pillar of your opinion?

A. I would not call that the foundation of my opinion. I believe it's one of my opinions.

Q. Well, and to be more precise, what you are saying is that the materials sprinkled on the external genitalia can never enter the vagina. Is that your opinion?

A. No. My opinion is that there's never been a study that demonstrates application of any particulate matter to the perineum can then be demonstrated to show migration of that particulate matter all the way to the ovary.

Q. Let's break that down.

Is it your opinion that talcum powder particles sprinkled on the exterior genitalia of a woman can penetrate through some circumstance into the vagina?

A. Do I think that could happen?

Q. Yes.

A. I think that probably could happen if those particles are dragged in there, say, through intercourse. But I don't think there is any

literature that has demonstrated the main hypothesis here in this case that something that is applied to the external genitalia can migrate all the way to the ovaries.

Q. I'm going to get to the ovaries in a few minutes. What I'm trying to do right now is discern very clearly what your opinion is with regard to whether powder sprinkled on the external genitalia can enter the vagina. Are you saying now that is possible?

A. I think it's possible, but I don't know of any studies that have demonstrated that.

Q. If a woman used Johnson's baby powder on herself every day, is it your opinion that if she were to have intercourse that day, that some of those particles might enter the vagina?

A. I think that's possible.

Q. And you do acknowledge some particle matter, when placed in the vagina, can migrate to the ovaries. Right?

A. Yes, I've seen some studies that have demonstrated that.

Q. And in terms of biologic plausibility, there is some data there could be particulate matter that can make it to the ovaries once it gets into the vagina?

A. There are a couple of studies that have demonstrated that particulates in a slurry can then be found in the fallopian tubes and ovaries under certain experimental conditions.
Q. Would you agree with me both of these diagrams demonstrate an open conduit from the vagina to the ovaries?
A. I can't actually see that one, sir.
Q. I brought two diagrams because I couldn't decide which one to use, and I think they both demonstrate the same point. But the point is, these are cross-sections of a woman's reproductive tract. Right?
A. Yes.
Q. So when you look at a cross-section, you could see very plainly that it's an open conduit from the vagina all of the way to the fallopian tubes. Correct?
A. So I disagree with your drawings here, sir, because they do not include at all the external genitalia.
Q. I've moved past the external genitalia to the internal reproductive.
A. But that's part and parcel of why it is not an open conduit.

Q. That's why I'm breaking this down into two sections.

We just talked about powder sprinkled on the outside can get inside under certain circumstances such as intercourse; and now I'm talking about particles, once they get inside the vagina, there is an open conduit all the way to the ovaries. Right?

A. So, again, the vagina is not wide open like that. It is collapsed. And the studies that you drew my attention to earlier involve placing particles in the posterior fornix at the mouth of the cervix in a slurry. That's not the same thing as what your drawings are showing.

Q. We'll talk about some of those studies in a minute. I'm trying to get a foundation to figure out where we are starting from.

Have you read the expert report of Dr. Laura Plunkett in this case?

A. No.

MR. DEARING: Can you pull up 54, please.

Q. Dr. Plunkett identified 24 migration studies on the topic of particles and their ability to migrate from the vagina to the ovaries.

How many migration studies have you looked at?

A. In humans?

Q. In humans.
A. Three.
MR. DEARING: Can you pull up slide 5, please.
Q. Of course Dr. Carson and Dr. Clarke-Pearson discussed six migration studies just in the last two days. Are the three that you reviewed any of these six?
A. So first I would disagree with your characterization that all six of these are migration studies. The talc found in tissue, 1996, which is the Heller study, does not demonstrate migration. It simply identifies talc in the ovaries.
Q. Fair enough. I didn't mean to categorize it that way.
Let's talk about the Heller study since you mentioned it. This is a study that found talc particles in women who both acknowledge using talc for female hygiene and women who did not. Do you agree?
A. Well, the women stated they applied talc to their perineum. I don't know that they said they used it for female hygiene.
But, yes, the study examined the ovaries of women that applied talc to the perineum and compared them to the ovaries of women that stated they did not apply talc to the perineum.

Q. I just presumed they were doing that for feminine hygiene. But my mistake.

Did the scientists in the Heller study actually look at the ovarian tissue under a microscope and detect talc particles?

A. I don't recall exactly how they did that analysis off the top of my head, but I would be happy to look at that study, sir.

Q. We will. I want to stay focused on migration for the time being.

Were any of these six studies among the three that you just told me that you looked at when you formed your migration opinion?

A. So when I told you three, there were three before I read my report. I've since read a couple other of these studies. But prior to writing my report, I did read the 1961 and the 1979 study.

Q. Okay.

MR. DEARING: Can you put up 56.

Q. Would you agree with me both the FDA and Health Canada have determined that the ability for particles applied to the perineum -- I'm sorry -- particles applied to the perineum can in fact migrate to the ovaries?

A. So I would say that the FDA and Health Canada

have not determined that because this is not primary science. But they do make those statements, yes.

Q. To be specific, the FDA said:

"While there exists no direct proof of talc and ovarian carcinogenesis, the potential for particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable. It is therefore plausible that perineal talc and other particulate that reaches the endometrial cavity, the fallopian tubes, ovaries and peritoneum may elicit a foreign body-type reaction and inflammatory response that in some exposed women may progress to epithelial cancers. However, there has been no conclusive evidence to support causality."

So if the author of this statement has -- no doubt he used the word "indisputable" as to whether talcum powder applied perineally can ascend to the ovaries. Correct?

A. That's what they say.

Q. Health Canada also looked at the issue and they said:

"Biological plausibility: Particles of talc are hypothesized to migrate into the pelvis and ovarian tissue causing irritation and inflammation. The presence of talc in the ovaries has been

documented," and that's the Heller study. "This evidence of retrograde transport supports the biologic plausibility of the association between perineal talc application and ovarian exposure, however, the specific mechanisms and cascade of molecular events by which talc might cause ovarian cancer have not been identified."

And that's the Taher study. Have you read the Taher study?

A. I have.

Q. Do you believe the author on behalf of Health Canada also says it's biologically plausible talc used on the perineum can ascend to the ovaries and actually cause an inflammatory response?

A. Well, what they actually say is that it's a hypothesis, and that's in the very first line. They don't have the same conclusion that you are drawing that it necessarily happens. They are putting forth that it's a hypothesis.

Q. Do you agree with them that evidence of talc in the ovaries has been documented?

A. Yes, and I believe that Heller showed that. But even Heller didn't know how that got there because the women that did not report perineal application of talc had shown talc in their ovaries.

Q. And the women who did not report using perineal talc, I think a half dozen or so, isn't it true --
A. I'm sorry. It was actually 12.
Q. Okay. Isn't it true of those 12 women who did not report using talc perineally, that they either gave a positive history of being diapered with talcum powder or they didn't know whether they were diapered with talcum powder?
A. So what Heller reported was that since they denied using perineal application of talc, she hypothesized that perhaps they had been diapered when they were children with talc.
Q. Well, six of the women actually stated affirmatively that they knew they were diapered with talc. Do you remember that?
A. No, not specifically.
Q. Can you pull up PSC 80. This was the IARC 2012 monograph excerpt.

Are you familiar with this monograph?

A. No.
Q. Would you turn to page 232. This is in your binder, if you prefer to look at it there. I'm going to show you a short excerpt. Hopefully you could see it from there.

Down at the bottom left-hand corner, where it

says "human exposure," that this is IARC explaining human exposure to cosmetic talc, and I would like to read this to you. They are describing exposure of the general population, and what they are saying is:

"Consumer products, cosmetics and pharmaceuticals are the primary sources of exposure to talc for the general population. Inhalation and dermal contact through perineal application of talcum powders are the primary routes of exposure."

Do you agree with that statement of IARC that the primary route of exposure for women would be either inhalation or perineal application of talcum powders?

A. So I've not studied, nor do I have an opinion on the inhalation of talc.

Q. Okay.

A. I only focused my review on the perineal application of talc.

Q. And I knew that. I only mentioned inhalation because they do. I'm more focused on the perineal application.

Do you disagree with IARC that the perineal application would be the primary exposure source for a woman for talcum powder?

A. I have no reason to disagree with this

statement. But I've not studied any other type of application.

MR. DEARING: Would you pull up PSC 5, please. That's the Langseth study.

Q. Are you familiar with the Langseth study?

A. Which one?

MR. DEARING: Can you blow up the title and the date, please.

Q. Are you familiar with this study?

A. May I see the abstract to see if this is one that I've reviewed?

Q. It's in your binder. It's PSC General Causation Exhibit 5. In my second binder it's the first study.

Can you read the abstract?

A. Yes.

I don't know that I've actually seen this particular paper. If it's in my report, then I have, or in my additional lists, but I don't know that I've actually seen this particular paper.

Q. As you sit here right now, you don't remember this paper, is that what you are saying?

A. As I sit here right now, I don't remember this paper.

Q. Look at the second paragraph of this first page. What it says is:

"From pathological studies it is known that particles and fibers that enter the body can migrate to distant organs. For instance, asbestos fibers have been found in ovaries from women exposed to asbestos. Analogously following perineal application, talc particles can migrate from the vagina to the peritoneal cavity and the ovaries."

Did I read that correctly?

A. Yes.

Q. It goes on to say:

"A majority of woman experience retrograde menstruation. This suggests a mechanism by which talc particles can travel through the female reproductive tract to the ovaries. Furthermore, epidemiological studies have shown decreased risks of ovarian cancer after tubal ligation and for hysterectomy suggesting that removing a pathway by which carcinogenic substances can reach the ovaries reduces the risk."

Do you agree with the statements in that paragraph?

MR. WILLIAMS: May I interpose an objection? My book from plaintiffs does not have PSC 5. It's missing. I want to make sure I know which Langseth we're talking about.

MR. DEARING: I'll give you mine.

BY MR. DEARING
Q. Do you agree with the paragraph I just read?
A. So what the authors are putting forth here in their introduction is, again, more of the hypothesis that talc applied to the perineum can make it to the vagina and the ovaries. That's a hypothesis. There is no data, if you will, that that actually occurs.
I do agree that retrograde menstruation exists, but this is the authors putting forth the same hypothesis that we discussed earlier.
Q. Well, would you agree with me the first sentence is not a hypothesis; it's a statement of fact from pathological studies: "It is known that particles and fibers that enter the body can migrate to distal organs."
You agree with that statement, don't you?
A. I agree with that statement, but I don't know where those things are getting in because they are not specific about talking about the entry.
Q. Are you aware that the talc particles that are found in the bottles of Johnson & Johnson Baby Powder and Shower To Shower average to be about 5-to-10 microns in size? Are you aware of that?
A. No. I have no opinion on the size of talc particles.

Q. Just to show you I'm not making this up --

MR. DEARING: -- can you pull up plaintiffs' PSC Exhibit 76. This is the Cramer 2007 study.

Q. And I think you may have referenced it in your direct examination.

A. I don't believe so, sir.

THE COURT: She did, 2016.

MR. DEARING: Okay. I'm sorry.

Q. If you would, please, take a look at the second page of this study. It's also in your binder. All of these will be in your binder.

MR. DEARING: The second page of the study, and if you could highlight on the left-hand column about two thirds of the way down in that paragraph where the sentence starts "scanning electron microscopy."

Q. Now, these are scientists from Harvard, right? Dan Cramer, Dr. William Welch, Dr. John Godleski. Are you familiar with those names? They've published several times in this area.

A. I'm familiar with Dr. Cramer's name, and I'm familiar with Dr. Godleski's name. I'm not familiar with Dr. Welch.

MR. WILLIAMS: Your Honor, may we have the exhibit number again?

THE COURT: It's 76.

MR. WILLIAMS: Thank you.

BY MR. DEARING:

Q. Dr. Godleski's name is familiar to you because the two of you have actually testified in two of the same cases. Right?

A. I've never seen Dr. Godleski testify, but I have no reason to not believe you, sir.

Q. He's a pulmonary pathologist, but he's also an analytical microscopist. He specializes in scanning electron microscopy. And, so, in this study they were looking at the presence of talc in the pelvic lymph nodes of a woman, and what they observed was that the talc particles they saw they averaged in range from 5-to-10 microns in size.

So to read from the study, it says:

"Scanning electron microscopy revealed plate-like particulates in the 5-to-10-micron range within the lymph node, in which energy dispersive X-ray spectroscopy showed a magnesium and silicate signature compatible with talc."

What he's saying is they observed talc particles in the pelvic lymph nodes that were in the 5-to-10-micron range of a woman with a history of genital talc use. Are we in agreement on that?

A. I agree that it says what you just read. For purposes of time, I'll agree with you she might have used perineal talc, but you have not actually shown me that.

Q. The talc particles, the size of them in this study were 5-to-10 microns. Do you agree that's their finding?

A. That is their finding.

Q. And I'd also like to direct your attention to Exhibit P-SC 56. That's the Health Canada report.

Have you seen this assessment?

A. Yes.

Q. It's been talked about a lot during these proceedings. They say something interesting on page 23 in the second paragraph.

So when they studied the size of these talcum powder particles, they discovered that the median particle sizes were ranges from 1.7 to 2 microns.

See where they found that right in the middle of that paragraph? The overall range was anywhere from half a micron to 8 microns, but the median range was 1.7 to 2 microns.

Is that a fair reading of that?

A. Yes.

Q. Here is where I'm going with all that. For

purposes of reference, a human hair is about 50 microns in diameter. Right?
A. I have no idea.
Q. You can Google it. It will say that I promise.
A. I don't have my phone.
Q. Here is the point. These talc particles that the women are sprinkling on their external genitalia are extremely small fractions of the diameter of a human hair. Would you agree with that?
A. I'll go with you on this.
Q. The reason I'm saying that's important is because with each application, a woman is pouring millions, perhaps billions of talc particles on her genitals. Right?
MR. WILLIAMS: Assumes facts. Lacks foundation.
THE COURT: Sustained.
BY MR. DEARING:
Q. Knowing now what the size of these particles are, is it still your opinion that this closed system prevents talcum powder particles from entering the vagina?
MR. WILLIAMS: Same objection.
THE COURT: Well, assuming that the size is as reflected in this report -- now ask your question.

BY MR. DEARING:

Q. Assuming that the size is as reflected in this Health Canada report and this lymph node study by Dr. Cramer and Dr. Godleski, is it still your opinion that talc particles cannot enter -- that talcum powder placed on the external genitalia cannot enter the vagina?

THE COURT: I'm not sure this is where the size came from. Did it come from Cramer?

MR. DEARING: This is Health Canada.

THE COURT: I'm confused. Why don't you start your question again.

Q. My question was: Now that you had an opportunity to review Dr. Cramer and Dr. Goldleskit's lymph node study where they identify the size of particles they found and --

THE COURT: I don't think that's fair to say now that she reviewed the study. She said she didn't. Ask the question as presented and the excerpt you had, assuming that to be the case.

MR. DEARING: Okay.

Q. Can we go back to the Health Canada, please.

Assuming that these measurements are accurate and the median particle size of cosmetic talc is 1.7 to 2 microns. Is it still your opinion that these

talc particles cannot enter the vagina after they have been applied to the external genitalia?

A. So two things: One, I believe you are misstating my earlier testimony where you asked me if it was possible, after the perineal application of talc, if a woman has sex, could a talc particle get dragged into the vagina, and I said I think that's possible.

And, two, nothing that you have presented to me with these two papers or the IARC monograph section that we just saw changes the opinions in my report or that I gave at deposition or that I have given here this morning.

Q. Okay. Is it your testimony that talcum powder applied to the external genitalia cannot enter the vagina just through normal movements throughout the day that a woman might make?

A. I do not believe that it does, sir, and I do not know of any study that shows me that particulate matter applied to the external genitalia moves into the vagina with normal activity.

Q. Is it your opinion that intercourse is the only way that talc applied externally can get into the vagina?

A. So I would say that any talc or particulate

that's placed on the external genitalia, if you then convert that external exam into an internal exam by entering the vagina with a substance, either intercourse or speculum or your fingers, that would be a vehicle by which the talc could be dragged in.

Short of that, where you are moving from an external application without actually doing some sort of internal penetrance into the vagina, I do not believe that the talc gets into the vagina.

Q. So are you saying that the author of the FDA statement we read a minute ago, who used the word "indisputable" and the scientists at IARC just got that wrong; that perineally-applied talcum powder can't enter the vagina?

A. So IARC actually says in the talc monograph that the evidence for migration is weak. So I'm not disagreeing with that. The statement by the FDA that migration is indisputable, I don't honestly know where that comes from. And from my research, I don't see any evidence of what we have been talking about here all morning long.

Q. Would you agree that studies that suggest that the perineally-applied talcum powder can enter the vagina and migrate to the ovaries? Would you agree that by concluding that it can migrate, they are

presuming that it can enter the vagina from the external genitalia?

MR. WILLIAMS: Calls for speculation.

THE COURT: I'm not even sure what the question asked. Could you rephrase the question.

MR. DEARING: Sure.

Q. We talked about some studies that opine that perineally-applied talcum powder can migrate to the ovaries. But not many of the studies say it can get from the outside of the vagina to the inside of the vagina.

My question is: Based on your reading of those studies, isn't it presumed by those authors that it can get from the outside of the vagina to the inside of the vagina before it migrates?

A. I think that's their hypothesis. But no one has any data. So to actually I think correct what you just said, I think you said not many studies show that it gets from the perineum to the vagina when, in fact, there are no studies that show that.

So I think the hypothesis is that it must get from the outside, i.e., the external genitalia to the vagina in order to again further migrate to the ovaries.

Q. Is the reason you are not willing to accept the

proposition that externally-applied talc can get inside absent being forced in there by the way that you have described, is the reason that's your position because there are no studies that show that talcum powder applied to the outside of the vagina can get to the inside of the vagina?

A. It's not simply that. It's also that the female genitalia in toto, starting with the lower genital tract and the labia minora, women are not an open conduit. When we go to the ocean and swim in the ocean, you don't get out of the water and have a big gush of ocean water come out of your vagina. It's not an open system. That's not what it is. It's only an open system when we separate the labia and put something physically into the vagina to expand it.

So it's not just that there is not a study. It's my experience as a gynecologist, as a GYN oncologist, and honestly as a woman.

Q. Are you aware that several Johnson & Johnson experts have affirmed that particles can migrate from the perineum to the ovaries?

A. What do you mean by "affirm"?

Q. Doctor Michael Birrer, are you familiar with him?

MR. WILLIAMS: Objection. Relevance. It's

not before the Court.

BY MR. DEARING:

Q. Doctor Birrer is an expert in the MDL. He offered a report in this case. His opinions are before the Court.

MR. WILLIAMS: I'm waiting to see what they read from.

THE COURT: I'll wait too.

MR. DEARING: I was going to offer opinions from other proceedings from that expert on this topic.

MS. O'DELL: Your Honor, if the issue is testimony from a state court case, certainly in the examination of Dr. Longo, I think the entire examination essentially was reading testimony from other proceedings. So I think it is certainly in keeping with that examination.

MR. WILLIAMS: The difference --

THE COURT: It was Dr. Longo as the witness reading his prior testimony. We're talking about presenting her with testimony of another expert that is not her, and what that person said and trying to cross her about that. Presenting a witness on the stand, an expert with his own testimony is absolutely permissible. That's not what we have here. If he presented testimony from her in another case, that

would be fine.

MS. O'DELL: I understand.

MR. DEARING: Okay.

BY MR. DEARING:

Q. Can you turn your attention to Plaintiffs' Exhibit 14. This is Blaustein's "Pathology of the Female Genital Tract." Are you familiar with this textbook?

A. I'm not sure I'm familiar with that edition, but I am familiar with one of the editions.

Q. This is the most current edition, the 6th Edition.

A. I know I don't have that.

Q. If you look in the 6th Edition on page 681 --

(Pause.)

A. Okay.

Q. This is in Chapter 14. This is the textbook, incidentally, the primary editor is Dr. Robert Kurman. Do you know Dr. Kurman?

A. Not personally.

Q. You know he is an expert for Johnson & Johnson in this litigation. Right?

A. Yes.

Q. If you turn to Chapter 14, the title of this chapter is "Surface Epithelial Tumors of the Ovary."

That's what we are talking about, right, ovarian cancers?
A. Yes.
Q. If you turn to page 681, in the section, "Reproductive Factors" he talks about several things. Then he talked about -- he also talks about "surgically induced protective factors that include hysterectomy, tubal ligation, and bilateral salpingo oophorectomy."
Doctor, I know you are not fond of the term "protective factors," but you know what he's talking about are factors reducing a woman's risk of getting ovarian cancer?
A. Ovarian cancer has been shown to be at a decreased incidence in women with some of these factors. But I would offer that the literature on hysterectomy is inconsistent. I would agree with tubal ligation and bilateral salpingo oophorectomy.
Q. So what Dr. Kurman writes is that,
"In addition, hysterectomy and tubal ligation prevent the introduction of a variety of potential environmental carcinogens from entering the peritoneal cavity and thereby coming into contact with tubal and ovarian tissue."
Doctor, do you agree with me that what Dr.

Kurman is saying, if you close off the fallopian tubes, it protects a woman from environmental exposures that make it into the vagina? Right?

A. I think you might want to -- that make it into the vagina?

Q. By closing off the fallopian tube, what he is saying here is that you are protecting the woman from environmental carcinogens. Environmental carcinogens means carcinogens outside of the body that are getting into the vagina. Right? That is what he is talking about, and then into the reproductive tract.

A. So that's a hypothesis. And there isn't a single citation there for that statement. There is some other literature, specifically, on tubal ligations and why tubal ligations may actually reduce the risk of developing ovarian cancer other than it simply being due to retrograde migration.

Q. Okay. You say this is a hypothesis. But this is the explanation he is offering in a well-recognized textbook for medical students and residents. Right?

A. Hypotheses exist in well-recognized textbooks all the time. That's not a statement of fact and there is no citation there.

Q. Okay. While I have this book open, I want to point to some other things that I want to talk about

in a few minutes.

The very next page in this chapter he talks about inflammation. Do you see that section on inflammation that I've marked?

A. Yes.

Q. It says:

"It has been suggested that inflammation potentially incited by ovulation-induced surface damage, by retrograde menstruation, induced salpingitis, or by the introduction of foreign material through the vagina and uterine cavity plays an important role in ovarian carcinogenesis."

Did I read that correctly?

A. Yes, you did.

Q. So Dr. Kurman is suggesting there is that -- there are suggestions among the gynecologic community and pathologic community that inflammation can occur because of the introduction of foreign material through the vagina and uterine cavity, and that it plays an important role in ovarian carcinogenesis. Do you agree with me that is what he is trying to explain?

A. Well, I agree that, again, he is putting forth that hypothesis. But, in particular, for the component of the sentence that refers to the

migration, again, there is no citation. And he even uses the word "suggested." Suggestion is a hypothesis. That's not primary science.

Q. While I'm on this page, the very next section says "other risk factors" and it reads:

"Other potential risk factors have been studied, but associations with ovarian cancer risk are weak or inconclusive. These include the body mass index."

That's the obesity you were talking about before?

A. Yes.

Q. (Reading continued.)

"Age at birth of first child, breastfeeding, weight, diet, talc, smoking, certain types of viral infections in childhood, and ionized radiation."

Do you agree that those with the exception of talc are recognized risk factors for ovarian cancer?

A. All of those factors have been evaluated in the literature at one point or another, and there have been different calculated odds ratios, yes.

Q. I have a whole other section on risk factors.

THE COURT: If you are going to a new section, we'll break now for lunch.

45 minutes, please.

THE DEPUTY CLERK: All rise.

(The luncheon recess is taken.)

(Continued on the next page.)

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A F T E R N O O N S E S S I O N

(In open court.)

THE DEPUTY CLERK: All rise.

THE COURT: Thank you.

CHERYL C. SAENZ, resumed.

CROSS-EXAMINATION (Continued)

BY MR. DEARING:

Q. Dr. Saenz, where we left off, I was just showing you where Dr. Robert Kurman, one of Johnson & Johnson's experts in this litigation, identified in his textbook perineal talc use as a potential risk factor in ovarian cancer.

You said one example of a way talcum powder can get from the outside of the vagina to the inside is intercourse, or some forceful mechanisms. I don't think those were your words, but that's what I understood you to say.

Would that also include tampon insertion?

A. I think I used the word penetration. So theoretically, yes. And as we actually saw earlier this morning, we know that talc can be on diaphragms and women put those in. That would be a way of

getting it into the vagina as well, so Blaustein's Pathology book is not the only book that suggests a woman's reproductive tract is an open conduit.

I would like to show you what is marked as Exhibit P-SC 34. This is a medical illustration. Are you familiar with Netter?

A. Not in the last 20 years have I looked at Netter.

Q. Netter describes the vagina from the Latin, "literally sheath or scabbard, serves as the portal to the internal female reproductive tract and the route of egress for the fetus during delivery."

So Dr. Netter describes it as a portal from the outside world to the inside.

Are you familiar with Baggish and Karram?

THE COURT: Was there a question? You just read from that book but you didn't ask anything.

Q. Do you agree the vagina serves as a portal from the outside world to the inside of a woman's reproductive tract?

A. The vagina serves as an organ that is in between the outside world, i.e., the external genitalia, and the upper genital tract, and it is an organ that babies pass through as they are born.

Q. Some of these questions seem elementary, and I

apologize for that, but I want to make sure that we are clear on what your testimony is.

Are you familiar with the Atlas of Pelvic Anatomy and Gynecological Surgery?

A. No.

Q. By Baggish and Karram. This is PSC 33?

A. No.

Q. This is a current textbook. If you turn to the chapter on the anatomy of the vagina, the first sentence says:

"The vagina is a potential space that connects the lower portion of the uterus, cervix to the outside environment."

Do you agree with that statement?

A. I agree with it. But just so that we are sure what we are saying, "potential space" means it is not an open space. So that actually substantiates what I have testified to before, which is that the walls of the vagina are collapsed on themselves; and the vagina is part of the lower genital tract. That's what that sentence says.

Q. It's not your testimony today all vaginas are the same, they are just alike. I can't believe I'm asking this question.

A. I think you need to specify a little bit more

what you are asking me.

Q. Are you familiar with Crum's Diagnostic Gynecologic and Obstetric Pathology?

A. No.

Q. This is the 2018 version of this textbook. If you turn to Chapter 24, entitled "Assessing Pelvic Epithelial Cancer Risk."

THE COURT: Do you have an exhibit number?

MR. DEARING: S 35.

Q. Chapter 24 is entitled, "Assessing Pelvic Epithelial Cancer Risk and Intercepting Early Malignancy."

A. Can you show me the title, please.

Q. Sure.

A. Thank you.

Q. There is a section on talc exposure here. What it says is:

"Talc placed on the perineum may enter the vagina and ascend to the upper genital tract. Structurally similar to asbestos, there is theoretical concern talc may potentially increase ovarian cancer risk."

Do you agree with that statement that talc placed on the perineum may enter the vagina and ascend to the upper genital tract?

A. No, and there is no citation there. That's just a statement. Additionally, the second sentence that you read had in it the word "theoretical" which is a hypothesis.
Q. The word theoretical had to do with what happens to the tissue when the talc ascends. That wasn't applying to whether it can ascend. Right?
A. No. The word "theoretical" applied to whether or not talc is associated with increased risk of developing ovarian cancer.
Q. The first sentence that I read says:
"Talc placed on the perineum may enter the vagina and ascend to the upper genital tract."
Do you agree with that statement?
A. No.
Q. So what I'm hearing you say is absent some forced penetration, there is no way for talcum powder particles to enter the vagina from the external genitalia. Is that what you are saying?
MR. WILLIAMS: Misstates testimony, your Honor.
MR. DEARING: I'm asking her if that is her testimony.
THE COURT: Do you understand the question?
THE WITNESS: Yes, your Honor.

THE COURT: Can you answer it?

THE WITNESS: Yes, your Honor.

THE COURT: Go ahead.

THE WITNESS: Sir, I never used the word "forced." I said that there must be something that actually penetrates into the vagina if there is going to be the possibility of carrying a talc particle with it from the external genitalia into the vagina. "Forced," is your adjective.

BY MR. DEARING:

Q. I'm trying to understand what you mean by "penetrate." Can you explain in layman's terms what you are talking about.

A. Put into.

Q. Are you saying if the talc particles are not put into the vagina, they can't get in there just through natural activities?

A. What do you mean by "natural activities"?

Q. Walking, sleeping, running, sitting.

A. I do not believe that any of those activities would carry a talc particle from the external genitalia into the vagina, and I do not know of any studies that would support that hypothesis.

Q. Is it your opinion talcum powder is safe to use on the perineum for women?

A. Yes.
Q. If talcum powder was 50 percent asbestos, would you still say it was safe for women to use?
A. If it were 50 percent asbestos?
Q. Yes.
A. No.
Q. You would not say it's safe to use?
A. I don't know what the constituent particles are within talcum powder. But if you are giving me a hypothetical, I would say I wouldn't advocate for anybody to put anything that's 50 percent asbestos on their body. But the literature, as it stands now on this particular topic, does not support a causal association between perineal application of talc and the development of ovarian cancer.
Q. So is the reason that you will not recommend someone to use powder that was 50 percent asbestos on the perineum is because it might get into the reproductive tract?
A. No. I wouldn't recommend anybody use anything that's 50 percent asbestos in any aspect of their life.
Q. I asked a minute ago whether all vaginas are designed -- or whether they all are anatomically the same. I don't remember what you said. I'm sorry.

A. I asked you to define that a little better.
Q. Are they all anatomically shaped the same?
A. No.
Q. Would you agree some are more open than others?
A. Open to what?
Q. Just open, like not overlapping where the labia is not overlapping.
A. No, the labia are opposed.
Q. I would like to show you my least favorite study, that's PSC 31. This is a study by a British scientist. It's called Lloyd from 2005. Are you familiar with it.
A. No.
Q. So you get a sense of what this study was about, they were actually measuring -- they were taking dynamics, measurements of external genitalia of women, and it was to benefit surgeons contemplating cosmetic surgery for patients or other types of surgery. But it was a population of 50 premenopausal women having gynecological procedures not involving the external genitalia and under general anesthetic.

So they are very graphic in this study to point out several anatomic features of the normal vagina.

Can you go to the next page and pull up that

diagram. This is the diagram they chose to use to show how they were measuring the anatomic points of the vagina. Would you agree with me that's not overlapping labia at all?

A. What position are these women in?

MR. DEARING: Well, can you zoom back out. Can you go to the results section.

Q. I'm not sure what position that woman was in, but they were using it to show what they were measuring, what dimensions, top to bottom.

Does it make a difference?

A. Absolutely.

Q. Explain that to me.

A. If they are lying supine, and I assume they are because these women were under general anesthesia, and their legs are up in a lithotomy position, that's going to extend their external genitalia and physically pull them apart even without somebody separating them with their fingers.

So that is not the way that the external genitalia rest on each other in a woman that's sitting or standing.

Q. Wouldn't you agree with me there are certain movements in everyday life of a woman that would allow for that separation you are talking about, maybe not

to the extent you are describing, but just some separation just in every day movement?
A. What types of movements?
Q. Running. Wouldn't that cause some kind of separation?
A. No.
Q. What about sleeping with your legs apart?
A. No.
Q. What about sleeping with a pillow between your knees?
A. No.
Q. Is it your testimony under no circumstance does a vagina open significantly enough for talcum powder particles to get in, unless they are being penetrated, to use your words?
A. Or if, as I suspect in this diagram, this photo you just showed, they are in a lithotomy position where their legs are extended, elevated, and the external genitalia are being separated physically.
Q. Would you agree with me invasive serous ovarian carcinomas are by far the most common of all the epithelial ovarian cancers?
A. Yes.
Q. Would you agree with me they make up 80 to 90 percent of the epithelial ovarian cancers?

A. I think that number is a little high. I would say more in the range of 60 to 70 percent, but there are variances depending on what published study you are looking at.

Q. Would you be surprised the NCI Cancer Genome Atlas identified invasive serous ovarian carcinomas as making up 80 to 90 percent of the epithelial ovarian cancers?

A. I would need to see the reference for that because I think what that is referring to is specimens that were submitted for the goal of molecular profiling them. So I'm not entirely sure that's reflective of the disease incidence.

MR. DEARING: Can you pull up Plaintiffs' Exhibit 51 -- that's not right. That's wrong.

It's PSC Saenz 5. It's in your binder.

Can you pull up that first paragraph.

Q. This is from the National Cancer Institute, and it's from The Cancer Genome Atlas. That's the TCGA. Midway through it says:

"Ovarian serous adenocarcinoma, the cancer studied by TCGA, is a type of epithelial ovarian cancer and it accounts for about 90 percent of all ovarian cancers."

Do you see that?

A. Yes.
Q. Do you agree with that statement?
A. I think that's fine. I said, depending on what study you are looking at, the rate varies a little bit.
Q. Would you agree with me, high grade serous carcinoma is the most aggressive of the epithelial ovarian cancers?
A. I need you to define "aggressive." The reason for that is that high grade serous carcinomas are not as chemoresistant as some of the other tumors. So the adjective "aggressive" --
Q. How about most likely to metastasize?
A. I can't agree with that. I think all the ovarian cancers are likely to metastasize except for perhaps to the same degree the borderline tumors.
Q. Would you agree with me the five-year survival rate for invasive serous carcinomas for Stage III and IV is less than 15 percent?
A. Five-year survival?
Q. For Stage III and IV disease?
A. That's not the current statistics, no.
Q. Would you agree with me Stage III and IV serous, high grade serous has about an 80 percent recurrence rate?

A. Yes.
Q. The point I'm trying to make is high grade serous carcinomas are the most common and possibly the most dangerous of the epithelial ovarian cancers. Would you agree?
A. No. Again, that's primarily because high grade serous carcinomas -- actually, at least on the first go-around of treatment -- are very sensitive to chemotherapy. So most women with that cancer will actually go into remission for some period of time. They are not as hard to treat as, say, the mucinous or the clear cell histology.
Q. With an 80 percent recurrence rate, they are almost impossible to cure, aren't they?
A. All of the ovarian cancers, if they are first diagnosed at Stage III and IV are almost impossible to cure.
Q. Where I'm going with all of that is you cited the Gertig study and you discussed it earlier in your direct examination. Do you agree with me -- let me back up. In your report, you said you prefer the cohort studies to case-control studies because they were more, I think you used the term, maybe scientifically reliable for something like that.
A. I might have said credible because they are not

as subject to selection bias and recall bias.
Q. And so Gertig was one of the cohort studies you used to support your opinions. Right?
A. Gertig was the first cohort that was published in the year 2000, yes.
Q. Would you agree with me the Gertig study showed that women who applied talc one-to-six times per week had a statistically significant relative risk or increased risk of 49 percent?
A. Can you please show me that table, sir?
Q. Certainly.
MR. DEARING: Can you pull up PSC Exhibit 51, please. Can you blow up the title and the author.
Q. This is the Gertig 2000 study. Right?
A. Yes.
Q. If you will, look in the bottom of the first column. It states one of the findings, starting with the sentence:
"There was a modest elevation in risk for ever talc use and invasive serous ovarian cancer with a multivariate relative risk of 1.40 with a confidence interval of 1.02 to 1.91."
That's showing a statistically significant 40 percent increased risk for invasive serous ovarian cancer. Right?

A. Yes.
Q. And then, if you will, turn the page and go down beneath the chart. In the very right-hand corner of that page, they discuss some other relative risks, and what they specifically look at is women who used talc at least once a week, which is essentially the women in this MDL, and it says:
"The relative risk for ever talc users less than once a week and one to six times per week were noted 1.29" -- that's for the less than once per week -- "and 1.49 for one to six times per week."
Did I read that correctly?
A. Yes, you did.
Q. So this Gertig study that you relied on that you said is more scientifically reliable than the case-control studies actually says that women who used perineal talc use, at least once a week, have a statistically significant increased -- I'm sorry -- have an increased risk of 1.40 -- a 40 percent increased risk. Right?
A. Are we going back to the 1.4 or are we discussing the numbers you have up on the marquis right now?
Q. Let me back up. The 1.49, you see the confidence interval crosses 1. Does that mean you

absolutely should discard the results if the confidence interval crosses 1?

A. If the confidence interval crosses 1, it means the finding is not statistically significant, and what that means is that you can't tell that there is really a difference between your study group and your control group.

Q. The point is: This Gertig study that you rely on, that you said is scientifically reliable because it's a cohort study and not a case-control study, suggests that for invasive serous carcinomas, the most common type of epithelial ovarian cancers with an 80 percent recurrence rate increases a woman's risk by 40 percent. Right?

A. So, one, I think you are misstating my testimony. I did not say the cohorts were more reliable. I said I think they are more scientifically credible because they are not as subject to the biases of the case-control studies.

I also never said I don't find the case-control studies informative. You are correct, that in this Gertig study, which was the 2000 publication, there was a statistically significant finding for ever use of perineal talc and an increased risk of serous ovarian cancer.

But as we discussed earlier this morning, this study had a follow-up study 10 years later in which this particular finding did not withstand the test of time. So as more women developed ovarian cancer, there was no unique finding in the serous ovarian cancers, which speaks to the likelihood that this was a random finding within the Gertig study because there is no latency in the Gates study.

MR. DEARING: Can you pull up slide 10.

Q. This is a slide that has been used several times. This was shown to several witnesses already, but I wanted to go over it with you real quickly.

This is a summary of the meta-analyses and pooled analyses of the talcum powder ovarian cancer risk. I want to make one observation about it because the Court has seen this quite a bit.

Do you agree the forest plot confidence intervals shown on this chart are all statistically significant and that they are all right of 1?

A. Yes.

Q. Do you also agree these are in somewhat chronological order? But the 2018 studies are at the top. So the more these meta-analyses combine data subjects and the bigger the studies get, the smaller the confidence intervals get. Do you agree with that

observation?
A. It would appear from the forest plot that that is the case.
Q. And what that means, when the confidence interval is shrinking is that there is less and less chance that the results are the product of chance. Right?
A. That's correct. That's the definition.
Q. And would you agree, based on this forest plot, that the relative risk from these meta-analyses and pooled studies all fall within 1.2 to 1.4?
A. Yes.
Q. And when you put up a slide earlier today, or Mr. Williams put up a slide, and you were suggesting watching TV and taking Valium and eating processed meat increases the woman's risk of ovarian cancer, the literature on those things is not as robust as the literature on talc and ovarian cancer, is it?
MR. WILLIAMS: Objection to the preamble, your Honor. It misstates the evidence.
THE COURT: It wasn't exactly the testimony. Those were identified as things, and she explained why they are not precisely risks.
We'll go on.
BY MR. DEARING:

Q. Let's talk about risk factors. As I understand it, your opinion is that there are known risk factors that increase or perhaps decrease the risk of the development of ovarian cancer but genital talc use is not one of them. Is that a fair summary of your opinion?

A. Yes.

Q. When we're talking about a risk factor, we're talking about some exposure that increases the chance of developing a disease. Right?

A. Not always.

Q. Well, for purposes of talcum powder and whether talcum powder causes ovarian cancer and the risk factors for ovarian cancer that you talked about, are you referring to when you use the term, "risk factor," are you referring to exposures that will increase a woman's risk of getting ovarian cancer?

A. But not all risk factors are exposures.

Q. Okay. Well, that's maybe not a good word then. Is a risk factor something that increases a woman's risk of getting ovarian cancer?

A. I would say a risk factor is something that has been identified as being associated with the development of a disease.

Q. And you identified several risk factors in your

report. I'm not going to go through all of them.

You mentioned endometriosis, and you said endometriosis is a risk factor for endometrioid and clear cell carcinoma. Is that accurate?

A. Yes.

Q. And you said tobacco use is a risk factor for mucinous carcinoma. Right?

A. It's weak, but it has been associated with the development of mucinous ovarian carcinoma, yes.

Q. You said obesity increases a woman's risk for borderline tumors, clear cell, mucinous and endometrioid. Right?

A. Right. Again, that's another weak factor, but it has been associated with the development of those different histologic subtypes.

Q. So in identifying endometriosis, smoking and obesity as a risk factor, are you stating that those are things -- that those are biologically plausible contributors to ovarian cancer?

In other words, is it biologically plausible that obesity increases a woman's risk of ovarian cancer?

A. So I don't know that a biologically plausible mechanism has been attached to the development of ovarian cancer for each and every one of those risk

factors.
Q. But you are still willing to suggest that obesity is a risk factor for each of those four histologies?
A. Yes. That's because the epidemiological literature on that risk factor across case-control studies and cohort studies has found that consistent albeit weak odds ratio.
Q. You would agree with me that scientists don't know exactly how obesity increases a woman's risk for ovarian cancer. Right?
A. Yes.
Q. You cite Olsen, the Olsen study to support your inclusion of obesity in your list of risk factors. It's the Olsen 2013 study. Do you remember that?
A. I don't think -- if I recall, and I could be mistaken, I think Olsen is a review article. But if you have it and we can look at it, that would be great.
Q. Would you agree you cited it in your report to support your inclusion of obesity in the risk factor list?
A. Yes.
MR. DEARING: Will you pull up Saenz 2, please.

Q. This is a review from an ovarian cancer consortium of about 50 scientists. Right?
A. Well, they reference at least 25 different institutions. So I would be guessing. If you counted all those authors, I'll give it to you.
Q. I have not. I was guessing.
A. Okay.
Q. I want to look at the results section, which is page 5, and here is where they identified the results having stratified the different histologies. What they say is that the odds ratio for borderline tumors was 1.24. Clear cell was 1.06 --
A. Where are you, sir?
Q. Let me come back to this study and I'll find the data when I have more time to look at that.

Do you have any recollection as to whether the odds ratio for obesity in this Olsen study or any of the studies you have seen rise to the level of 1.49 as was identified in the last cohort study we just discussed for serous invasive?
A. So the relative risk in the Gertig study that was statistically significant was for ever versus never use and it was not 1.49. It was 1.40.
Q. I'm sorry. I misspoke.
A. And my read on the literature on obesity and the

literature that I've cited is that the relative risk on obesity is in the range of about 1.2 to 1.3. But if you have something showing me that there is something higher, I would be happy to look at it.

Q. That's exactly right. That was my point.

You testified earlier about genetic mutations, and probably the most influential risk factor I suppose is a genetic predisposition of ovarian cancer. Do you agree?

A. Yes.

Q. Would you also agree genetic mutations only make up about 1 percent of diagnosed ovarian cancers?

A. Epithelial ovarian cancers?

Q. Yes.

A. No, I would not agree with that at all.

Q. Would you agree only about one in 500 women test positive for the BRCA gene?

A. In the general population?

Q. In the general population, yes.

A. The data on that is quite variable because it depends upon identifying certain founder populations. For example, Ashkenazi Jewish women have the incidence of 11 percent for being positive for BRCA 1 and 2 mutations. There is a known Polish mutation, a French Canadian mutation. So I don't actually look at

general population statistics. I think the more useful metric is to look at women who have been diagnosed with ovarian cancer and what percentage of those women are found to be positive for a genetic mutation that has been inherited.

Q. So that I'm clear, is it your opinion that talc may be a risk factor for ovarian cancer, or it's absolutely no way it's not possible, it's not a risk factor for ovarian cancer?

A. So based on the current state of the science, it is not a risk factor for the development of ovarian cancer.

Q. Would you agree with me many reputable scientists disagree with you on that; many different reputable scientists and researchers do believe perineal talc use increases a woman's risk for ovarian cancer?

A. I know even based on this hearing that there are people that disagree with that opinion, but I don't think that they are looking at the literature correctly because it would not support the position that talc is a risk factor for developing ovarian cancer.

Q. It's been discussed in this hearing there are some institutions that failed to list talc as a risk

factor for ovarian cancer. I'm sure you are familiar with some of them. You talked about some earlier. Right? Organizations, I should say.

A. I still wouldn't characterize it as they failed to list it because inherent in that statement is a bias that they are not doing what they are supposed to do. They don't list it.

Q. Okay. Would you also agree with me there are academic institutions that do list talc as a risk factor for ovarian cancer?

A. There may be but I don't know what they are basing that determination on.

Q. You've been an attending physician at the University of California San Diego for about 20 years. Right?

A. Almost 21.

Q. And, specifically, you work at the Moores Cancer Center at UCC San Diego, right?

A. That's where my clinic and academic offices are.

Q. I took this quote from your report. We can look it up if you like.

The Moore Cancer Center, you described it as a comprehensive high quality patient center care. That's how you described the care that's being offered there. Would you agree with that description?

A. Well, an NCI designated comprehensive cancer center.
Q. Part of that comprehensive high quality care is to give information to the public when they are curious about certain topics on cancer. Right?
A. Yes.
Q. They maintain a website to do that, right?
A. UCSD and the Moores Cancer Center maintains several different websites.
Q. The website offered by Moores Cancer Center, it offers current accurate information about risk factors pertaining to ovarian cancer. Right?
A. I don't know the answer to that.
MR. DEARING: Well, can you pull up slide PSC 3, please. Actually it's slide 1.
Q. This is from the website from U.C. San Diego Health and the Moores Cancer Center.
If you click on, "What Do You Know About Reproductive Cancers?", they have you take a little test. I thought it was interesting, the answer to No. 6.
MR. DEARING: Can you blow up the right side of that slide.
Q. The answer to No. 6, and the question is in the answer:

"A woman's lifetime chance of getting invasive ovarian cancer is about one in 78. What are the factors that put a woman at risk for this cancer?"

They identify several of the risk factors: Family history, age, child bearing, personal history. Then it goes on to name some others. It says:

"Other possible factors include taking fertility medicines. These may slightly increase the risk of ovarian cancer. Talc may be a risk factor. Some studies suggest that women who use talc in the genital area for many years may be at risk. Hormone therapy may also raise the risk."

The last sentence says:

"Having one or more risk factors mentioned here does not mean that a women is sure to develop ovarian cancer, but the chance may be higher than average."

The fact that U.C. San Diego and Moores Center put this information about risk factors and this information about talc specifically in their website means that they have a different position on talc and risk factors than you do. Correct?

A. No, that's not correct.

Q. Do you agree with the statement that's up there that talc may be a risk factor?

A. No, I do not.
Q. If the institution is putting this information out there that says talc may be a risk factor and you are saying you don't believe that, don't you have a difference of opinion here?
A. May I explain?
Q. Sure.
A. So the information that is posted on the patient friendly websites, if you will, is posted by the marketing and communications department. They do not consult any of the physicians at UCSD. They contract with a third-party vendor and post what that third-party vendor posts at multiple institutions across the country.
Q. Are you telling me there is no one at Moores Cancer Center that monitors what goes on their website to the public?
A. That's what I'm telling you.
Q. That seems very risky.
A. I don't disagree with you. It doesn't make me happy but it is the way the marketing and communications department functions.
Q. Apparently, there is at least one medical physician and one nurse who oversees it, right; an online medical reviewer, Dr. Richard Lo Cicero. Do

you see that?
A. He's not a UCSD physician.
Q. Do you know him?
A. I don't know him. He is not in our division. He is not in the Moores Cancer Center.
MR. DEARING: Will you pull up PSC Saenz 8, please.
Q. Are you familiar -- this is a publication from Gynecologic Oncology. Do you subscribe to this journal Gynecologic Oncology?
A. Online.
Q. Do you recall if you have ever seen this -- this is called "Opportunities and Challenges in Ovarian Cancer Research," a perspective from the 11th ovarian cancer action HHMT forum in Lake Como in March 2007. Do you remember ever seeing that?
A. No.
Q. If you will, scroll down to the first page, the abstract. What this is, this is 50 or more of the world's leading ovarian cancer researchers --
A. Can you say that again?
Q. This is a list of the coordinators of this conference. One is them is Dr. Jeff Boyd, who is a defense expert. At this conference there were 50 or more leading researchers and --

A. I don't believe there are 50 authors, sir.
Q. I'm having a hard time seeing it up there. So let me look in my binder real quick.
(Pause.)
So on page 656, in the bottom right-hand corner, this is a list of the attendees. There are probably more than 50, I was estimating.
A. That's not necessarily who authored this paper. Right?
Q. I agree with you.
These are the attendees that are attending this consortium. Okay?
A. Okay.
Q. I suspect the authors are listed on the next page, and there are eight or nine of them. See them on the right?
A. Yes.
Q. What they say, if you go to the first page, second paragraph in the right column:
"A combination of demographic, reproductive and environmental risk factors might be used to develop a model that would more accurately predict risk," when they are talking about risk of ovarian cancer.
"One preliminary algorithm using seven risk

factors: age over 45, long-term genital talc use, family risk of ovarian cancer, or early onset breast cancer," and some other things, "showed that women with six to seven of these events have an odds ratio of 7.59."

The point I'm making here is this consortium back in 2007 seem to be identifying long-term genital talc use as a risk factor for ovarian cancer. Would you agree?

A. Well, they put that into an algorithm that they created in 2007. But as we sit here now, in 2019, no such algorithm exists in clinical practice.

Q. My point is all the way back in 2007, talc was being discussed as a risk factor for ovarian cancer. Do you agree?

A. Talc is being discussed as a risk factor for ovarian cancer since 1982, but that doesn't mean that it causes it. In fact, after this was published is when the Gates 2010 study came out. So the fact that this was proposed in 2007, I haven't stated that it wasn't being discussed back then. But we're now 12 years into the future, and there is no algorithm in clinical practice that plugs genital use of talcum powder into calculating a woman's risk of developing ovarian cancer.

Q. Okay. But there are many institutions and consortiums like this that continue to include perineal use of talcum powder a risk factor for ovarian cancer in their general discussions. Right?
A. I don't know what you are referencing.
Q. You offered some opinions about causation and inflammation on direct. I want to ask you a couple of questions about that.
I think you said there was no evidence that inflammation contributes to ovarian cancer, and to say that you were relying on the Merritt study. Am I recalling that correctly?
A. What I believe I said is that there is no data that chronic inflammation leads to the development of ovarian cancer. Merritt is only one of the studies that I looked at to support my opinion.
Q. Would you agree that inflammation does play a role in the initiation and development of many types of cancers?
A. Not ovarian cancer.
Q. But it does for others?
A. It does for certain cancers such as colon cancer.
Q. Are you familiar with the Savant 2018 study?
A. I think I've seen a review article by them.

MR. DEARING: Would you pull up PSC 115, please.

Q. Does this study look familiar?

A. It's not a study. It's a review article. It's not primary science.

Q. Does this review article look familiar?

A. Yes.

Q. Would you look at the abstract, please.

First of all, this is June 14th, 2018, actually published July 30th, 2018.

Do you see that?

A. Yes.

Q. It's by three scientists from the University of Indiana.

MR. DEARING: And if you would highlight the abstract, please.

Q. The first sentence of the abstract reads:

"Inflammation plays a role in the initiation and development of many types of cancers, including epithelial ovarian cancer, in high grade serous ovarian cancer, a type of epithelial ovarian cancer."

Do you see that?

A. I see that they wrote that.

Q. Do you disagree with them?

A. I don't see any citations for that. I don't see

this is as primary science, and I don't know of any primary science that supports that chronic inflammation initiates ovarian cancer.

Q. Would you go to the next page, please, top of the page, second line down, the sentence starts:

"Chronic inflammation is an important risk factor associated with epithelial ovarian cancer in high grade serous ovarian cancer, the most malignant subtype of epithelial ovarian cancers."

Do you see that?

A. I do see that.

Q. You still disagree with them?

A. Yes. And there is no citation.

Q. Would you go to page 3 of 30, first sentence of that inflammation section, it says:

"Amongst other factors, such as hereditary, environmental, and lifestyle, inflammation emerges as an important risk factor for epithelial ovarian cancer."

Still disagree with them?

A. Again, sir, there is no citation. This is a statement that's made without referring to any primary science.

Q. Let's look at some primary science.

Would you go to the next page, please, 2.2,

where it says "infection."

It says:

"Pelvic inflammatory disorder is the infection of the female reproductive organs, like the cervix, uterus, fallopian tubes, and ovaries, it is a significant risk factor for ovarian cancer."

You disagree with that?

A. There is literature to show pelvic inflammatory disease, one episode specifically does not increase a woman's risk of developing ovarian cancer. There is literature to also show that with two or more episodes of PID, that there is an increased risk specifically for borderline ovarian cancers.

So I don't just blanket disagree with that statement because there is some literature to support it in terms of women with repeated episodes of PID but for a very specific type of ovarian cancer.

Q. Okay. I know this question is obvious, but pelvic inflammatory disorder or PID is an inflammatory condition. Right?

A. It's an infection that leads to inflammation, correct.

Q. In the next paragraph it discusses other sources of inflammation, and it says:

"The other causes" -- let's go back up to

infection. It cites studies there in the next few lines. Since we are in agreement about that, I think I'm just going to move on.

Now, in the next section "other sources of inflammation," it says, quote:

"The other causes of inflammation in the ovaries and/or fallopian tubes are endometriosis, obesity, polycystic ovarian syndrome and talc exposure."

Do you believe that endometriosis causes an inflammatory reaction that may lead to some type of ovarian cancer?

A. So I think that endometriosis as a risk factor for developing ovarian cancer is a really complex issue. I don't think it's necessarily a yes or no answer because endometriosis in and of itself, which involves the implanting of endometrial glands on other organs in the pelvis, that implanting of the glands can cause a localized inflammatory reaction.

But the actual precursor lesion for the development of the cancer seems to be that those endometrial cells start to develop atypia which is a precursor lesion of the cancer itself and it's also found within the uterus within the endometrial cavity as endometrial cancer is developing.

So I think it's a complex issue.

Q. The sort of misplacement of those endometrial cells causes an inflammatory response, doesn't it?

A. It can, but it's not necessarily the cancer is developing from that inflammatory response as much as those endometrial cells are becoming precancerous themselves.

Q. These authors also ascribe an inflammatory process to the obesity risk factor, and it's a lengthy explanation I don't think we really have time for.

In the next paragraph they say:

"Obese women have higher risks of epithelial ovarian cancer and high grade serous carcinoma and pro-inflammatory cytokines are associated with higher body mass index levels."

Do you agree inflammation may play a role in the risk factor of obesity?

A. I don't think that has been worked out. I think that's a hypothesis.

Q. These authors also say that polycystic ovarian syndrome is a risk factor and a source of inflammation. Do you agree with that?

A. In and of itself I don't know, nor do I necessarily agree that polycystic ovarian syndrome is a risk factor for ovarian cancer. I think that gets

subsumed into women that are nulliparous. PCOS is a cause of infertility, and we know that infertility is a risk factor for developing ovarian cancer. So I think that's part and parcel of the infertility risk factor and not necessarily associated with an inflammatory condition.

Q. Okay. And the last source of inflammation they recognize that increases a woman's risk for ovarian cancer is talc exposure is 2.3, the first sentence.

I'm on 430, Section 2.3, at the very beginning of section -- it's page 4 of 30.

Of course you disagree with them on that as well. Right?

A. Well, yes. And, also, what you were looking at before, actually, really, got it wrong because I think the last paragraph that you highlighted, it said that talc could get to the ovaries from diaphragm use, and we know from what we looked at earlier this morning, having your diaphragm dusted with talc and using your diaphragm decreases the odds ratio.

Q. Isn't it true the instructions that come with the diaphragm tell you to rinse off the diaphragm before you use it?

A. I don't know. I've never used a diaphragm.

Q. The next page, 5 of 30, Sections 2.4, you were

also asked some questions about this on direct examination, and that's nonsteroidal anti-inflammatory drugs, and what these authors say in the first sentence is:

"Further connecting inflammation to EOC, epithelial ovarian cancers, are several studies that demonstrate that intake of nonsteroidal anti-inflammatory drugs, NSAIDs, specifically of aspirin, correlates inversely with risk of ovarian cancer and endometrial cancer." And they cite four studies.

Do you agree there are studies that show NSAIDs do reduce a woman's risk of ovarian cancer?

A. So what you've highlighted here agrees completely with what I said this morning, but that only further demonstrates the inconsistencies within the NSAIDs, the literature, right, because using low dose aspirin daily decreased the risk of a woman getting cancer. But in some studies, using the non-aspirin NSAIDs actually increased her risk of getting cancer.

So if we're talking specifically about aspirin, it does. But then when we expand the conversation to the non-aspirin NSAIDs, which also are anti-inflammatory drugs, the risk of ovarian cancer has been shown to increase.

Q. At the time that you were formulating your opinions about whether talc can cause ovarian cancer and whether it would cause an inflammatory reaction in cells, you had not considered five seminal cell studies. You had not considered the Buz'Zard study. Correct?

A. Are you asking about when I wrote my report?

Q. I've got your report and your deposition. And according to your deposition, you hadn't considered any of these five I'm about to read. Tell me if I'm wrong.

A. I wouldn't say I hadn't considered. I hadn't read them. That's true. But I knew of the studies and knew what their findings were based on reading plaintiffs' expert reports.

Q. So at the time of your formulation of your causation opinions, and at the time of your deposition even, you had not read the Buz'Zard 2007 study, right?

A. That's correct.

Q. And you had not read the Shukla 2009 study, right?

A. That's correct.

Q. And you had not read the Fletcher Saed 2019 study, right?

A. So that's not exactly correct because I did not

read the published manuscript, but I had read Dr. Saed's report for this matter which he himself said in deposition testimony was the same thing as his manuscript.

Q. Okay. And you hadn't read the Akhtar 2010 or the 2014 studies?

A. Correct.

Q. And is it your testimony today, reading about studies gives you enough information to testify on the subject or the topic of these five studies beyond your expertise?

A. I would not say the topic of these five studies is beyond my expertise in terms of who I am as a gynecologic oncologist. But the topic of those five studies is not what I was retained to do in this matter.

Other investigators, if you will, M.D.s, Ph.D.s were being retained in this matter to weigh in on if the cancer biology, and that was not my understanding of what I was being asked to do in this matter.

Q. Could you put up 515, please? These are the five studies I'm referring to. I should have put this up earlier so you could see it.

I think you said you did know about the

studies. You just chose not to read them because you weren't asked to offer opinions on this topic. Am I understanding that right?

A. I knew about the studies, and I knew from reading the expert reports that none of these studies actually showed malignant transformation.

So reading them I did not feel was important to my opinion, and I knew that other people that basically are cancer biologists were going to be asked to evaluate the cancer biology questions in this matter.

Q. With the exception of Dr. Saed, because you read his report, someone told you about the results of these studies and how you deemed they were unnecessary for your opinions?

A. What I said was I read your expert reports, and they described these studies in their reports, and I knew from your experts' reports that none of these studies demonstrated malignant transformation.

MR. DEARING: Can you put up slide 9.

Q. Some other things you did not consider in forming your opinions, isn't it true you did not consider whether talcum powder contains asbestos in determining whether talcum powder use might contribute to cause cancer?

A. That's true.
Q. And you did not consider whether fibrous talc is contained in the powders and might contribute to cause cancer. Right?
A. Might contribute to cause ovarian cancer.
Q. Ovarian cancer, right.
A. That's true.
Q. And you did not consider the carcinogenic heavy metals in talcum powder in your analysis as to whether it could cause ovarian cancer. Right?
A. If talc is the vehicle by which you are saying all of these other things are getting to the women, then that is true, I did not consider the components within the talc. I focused on the baby powder itself, the perineal application of the baby powder.
Q. If the baby powder contains asbestos and/or fibrous talc and/or carcinogenic heavy metals and potentially carcinogenic fragrance chemicals, and you didn't consider those constituents, then you didn't consider baby powder in its entirety, did you?
A. Yes, I did because I focused on the literature that examined the perineal application of talc and whether or not the risk of ovarian cancer is increased. If talc contains all of these elements that you are purporting are in there, and that would

make the talc carcinogenic, there would be an increased risk of developing ovarian cancer with the perineal application, and that is not supported by the literature.

Q. If asbestos was in talc, and if it migrated to the ovaries, do you believe that it would cause an inflammatory reaction there?

A. Are we talking pure hypothetical?

Q. Yes.

A. Asbestos is a Group 1 carcinogen by IARC. I do not believe there is a risk, an increased risk with baby powder, the way that it is now, the way that it has been used since, it's been studied since 1982.

So I assume asbestos could cause an inflammatory response someplace, but it's not something I've studied.

Q. Do you have an opinion about whether asbestos can cause ovarian cancer?

A. So I know that IARC has published and stated that there is an increased risk of ovarian cancer in woman that have had heavy occupational exposure to asbestos, but I think there are problems with those studies. But that is what IARC said.

Q. And I'm asking Dr. Saenz's opinion, do you have an opinion on whether asbestos can cause ovarian

cancer?

A. It's unfortunately not a yes or no answer for me because I think that I acknowledge what IARC has published, but I think there are some problems with the studies that have been done, and not all the studies have shown an increased risk of developing ovarian cancer with heavy occupational exposure to asbestos. So I don't think it's as clear an issue as IARC has stated.

Q. That's exactly why we talk in terms of biologic plausibility. So let me ask you this question:

In your opinion, is it biologically plausible if talc contains asbestos and fibrous talc, or carcinogenic heavy metals, or carcinogenic fragrances, and it does reach the ovaries, isn't it biologically plausible that could cause an inflammatory reaction that may set in motion a cascade of a reaction that turns into cancer?

MR. WILLIAMS: Objection, your Honor. That's clearly not something Dr. Saenz has been asked to opine on in the matter. She already testified as to the limitations on her knowledge in that area. We don't think it's appropriate for counsel to ask her, a person who has indicated she is not an expert in asbestos to provide that opinion.

MR. DEARING: I believe that was asked on direct about biologic plausibility of talc, and if she's going to talk about talc, we have to talk about the constituents that are in talc.

THE COURT: I'll let the Doctor answer herself. I think she said she did not consider components. She's not an expert in heavy metals and asbestos. She considered talc as a whole, whatever may be in it.

I think that was your answer this morning?

THE WITNESS: Yes, your Honor.

THE COURT: That has been her testimony throughout, regardless of what she's looking at as a whole, but we can ask her that question and have her clarify at this time.

MR. DEARING: Let me ask the inverse of the question.

Q. Is it your opinion it's not biologically plausibility that talc can cause ovarian cancer, and is that opinion without regard to whether the talc contains asbestos, fibrous talc, carcinogenic heavy metals, or fragrances?

A. That's correct.

Q. You don't know whether if talc did contain those things, that would change your opinion because you are

not an expert in that field?
A. It would not change my opinion because the literature I looked at, talc literature, so if there were components within the talc that are getting to the woman via the talc, the talc literature would show an increased risk of ovarian cancer, and it does not.
So my opinion is regardless of the constituents that are in the talc, regardless, perineal application of talcum powder does not increase the risk, nor does it cause ovarian cancer.
Q. Did I just hear you say there is no literature to suggest that perineal talc use increases a woman's risk of ovarian cancer?
A. The sum of the literature, the sum of everything we have been discussing here, looking at the sum of the case-control studies, looking at the cohort studies, the inconsistencies within the case-control studies, between the case-control studies and the cohort studies, the inconsistencies within the individual case-control studies, all of that, all of that is what I've examined as well as the literature on inflammation, the literature on NSAIDs, the slides on patients that have surgery, that have precursor lesions for ovarian cancer that do not show inflammation, all of that is what I have used to form

my opinion.
Q. With regard to those slides, isn't it true that if you are looking at a slide of tumor tissue, you will not expect to see the precursor lesion that initiated that cancer process because it's obliterated by the tumor?
A. I'm not talking about the slides where the cancer already developed. I'm talking about the slides that are on the women who have had prophylactic surgery, and we can identify the STIC lesions and the p53 signatures which are the precursors to the high grade serous carcinomas. There is no inflammation there.
So if those cancers are in the process of developing and you are proposing that chronic inflammation is the inciting event, that should be there, where the precancer is, and it's not.
Q. Are you screening the women that you are prophylactically giving oophorectomies to, whether they are talc users? Are you asking them that question?
A. No, but your hypothesis is that even exclusive of talc, that chronic inflammation is causing ovarian cancer. And what I'm saying is talc or not, chronic inflammation is not causing the high grade serous

carcinoma. The biology doesn't bare that out.
Q. But you can tell postmenopausal, by looking at pathology slides of an ovarian cancer tumor?
A. That's not what I'm saying. What I'm saying is I'm looking at the precursor lesions, and there is no inflammation.
Q. I guess my problem is, if you remember looking at what you are calling precursor lesions, but you can never take the tumor and trace it back to those precursor lesions, because the precursor lesion here gets destroyed and subsumed in the tumor. So you are speculating whether those precursor lesions will morph into a cancer. Right?
A. Not entirely true and not supported by the science.

So one of the criteria for diagnosing fallopian tube cancer as opposed to cancer that originated in the ovary is that somewhere in that fallopian tube, as you examine the entire fallopian tube, you need to find that STIC lesion. That's how the pathologists said this came from the fallopian tube as opposed to the ovary.

So not entirely true. It's a precursor lesion that allows you to call out and say this is fallopian tube carcinoma. So you might have a big old tumor but

you also have to have evidence of the spectrum, if you will, of development.

Q. You talked some about the Society of Gynecologic Oncology, the SGO. You are a member of SGO. Right?

A. Yes.

Q. You are a member of ACOG. Right?

A. I'm a fellow, yes.

Q. You are a member of the American Congress of Obstetrics and Gynecology?

A. Yes.

Q. Are you Board Certified in OBGYN?

A. Yes.

Q. Are you Board Certified in gynecologic oncology?

A. Yes.

Q. When did you become Board Certified in gynecologic oncology?

A. 2001.

Q. How do you become Board Certified in gynecologic oncology?

A. Well, you have to complete a fellowship successfully, and then at the completion of your fellowship, you take a written exam, and then you -- it's different now than when I did it. You don't have to -- I think for me, when I did it, I had to wait 1 1/2 to two years before I could collect cases to sit

for my oral examinations.
Q. Once you become Board Certified, what do you have to do to maintain it? Do you have continuing education requirements?
A. We do.
Q. Is that the only thing you have to do to maintain it?
A. I think you have to maintain hospital privileges in good standing and submit to the Board that you have that, and your maintenance of Certification means that you have to read 30 articles a year that are posted online, answer test questions about those articles, and receive a passing score, and you have to every year do at least two different chart pulls, if you will, to make sure your practice is consistent with certain objectives of the field.
Q. Who makes up the American Board of Obstetrics and Gynecology? Is it other gynecologic oncologists around the country?
A. No, it's general OBGYNs, maternal, fetal, medicine specialists, some gyne-oncologists --
Q. Is there a subspecialty you can be Board Certified in, and that's gynecologic oncology?
A. Yes.
Q. Is it the same Board that oversees both the

General American Board of Obstetrics and Gynecology and the Gynecologic Oncology Board Certified?
A. Yes.
Q. Have you ever served on the American Board of Obstetrics and Gynecology?
A. No.
Q. Have you ever served on any of their committees?
A. Not on the Board's committees, no.
Q. Do you know Dr. Steve Plaxe at UC San Diego School of Medicine? I only ask because I noticed he sits on the GYN Oncology Committee. Do you know him?
A. He is one of my partners.
Q. So being Board Certified in Gynecologic Oncology sort of sets you apart from, I guess, other non-Board Certified physicians as having demonstrated a certain expertise in that area. Would you agree?
A. Well, it means I have specialty training. But many people have specialty training. They are just boarded in their specialties. What you said sounds a bit elitest, and I'm trying not to sound elitest.
Q. Do you know whether the American Board of Obstetrics and Gynecologists recognizes talc as a contaminant that might cause cancer?
A. I don't believe the Board considers it a risk factor per se in the situation by which posting risk

factors because that's not the responsibility of the Board. I do know that the Board has this list of learning objectives per se that it puts forth for fellowship candidates to learn, and one of the subjects it talks about is talking about potential risk factors that are out there being discussed, and one of the learning objectives in terms of talking about environmental exposures, the Board does list talc as one of them.

Q. Let's look at Plaintiffs' Exhibit 13, slide 3. This is the guide to learning in gynecologic oncology. This gives you sort of an outline of the things you are expected to know about for the exam and be board certified. Right?

A. It's kind of a listing of topics that the fellow should be prepared to discuss in their oral examination. Can you go to the next page, please. That explains more in detail what it is.

Then if you would go to page 13, please. If you look at Roman numeral III, 8, subsection B 1(e).

Q. It says:

"The fellow should understand and be able to describe" and it lists all these things, and one is "environmental contaminants such as the relationship of talc and asbestos to ovarian and other malignancies

and smoking to lower genital track cancer."

Do you agree this is one of the topics the American Board of Obstetrics and Gynecologists specifically requires their physicians to know things about in order to become Board Certified?

A. So this listing is a list of topics that the fellowship candidate should be prepared to discuss and review the literature in order to be a responsible gyne-oncologist, yes.

Q. The topic suggests that "environmental contaminants such as the relationship of talc and asbestos to ovarian cancer and other malignancies" -- there is an implication in that statement those things are not theoretical, that there is an established relationship, and that's what it says. Right?

MR. WILLIAMS: That misstates the document, your Honor.

THE COURT: Let me have her answer the question, please, as to what she thinks that's saying.

A. I think that's your interpretation, because, in fact, what the Board wants is fellows and fellowship candidates to be responsible by doing a comprehensive review of the literature to come to appropriate conclusions. So, for example, right above the segment that you've highlighted they talk about viruses

including herpes. This is for GYN oncology. Herpes is not associated with the development of gynecologic malignancies. It used to be thought cervical cancer was caused by herpes, but now we know that's not true. So in the same vein, I think the Board is putting out there talc and discussed its relationship to ovarian and other malignancies because fellowship candidates should be prepared to have that discussion.

Q. HPV virus, that's not a theoretical cause of cervical cancer, is it?

A. No, but herpes is, and that's still listed because the Board wants the fellows to be able to have a discussion where they can say, we once thought this was the case for cervical cancer, but now we know it's not true. Likewise, the board would want educated fellows to be able to have a discussion about the relationship between talc and the development of ovarian cancer. They want their fellows to stay current.

Q. And just beneath that it says:

"Genetic mutations"-- and genetic mutations are not a theoretical cause of ovarian cancer, are they?

A. No, they are not.

Q. Where it says:

"Environmental contaminants such as the relationship of talc and asbestos," it doesn't say such as the theoretical relationship of talc and asbestos, does it?

A. It doesn't say that with the herpes either, but that is the case.

Q. It says that fellows should be prepared to have a discussion about talc and ovarian cancer. Yet you've told us you don't have that discussion with your patients. Right?

A. This is to be prepared for the board exam, sir. That's not the intent of this document.

Q. What's the purpose of learning about the relationship of talc and ovarian cancer if you are not going to share it with your patients?

A. If you get asked a question you can answer it in an educated format which I have said I do with my patients if asked.

MR. DEARING: That's all I have, your Honor. Thank you.

THE COURT: Let's take a break.

THE DEPUTY CLERK: All rise.

(Recess.)

THE DEPUTY CLERK: All rise.

THE COURT: Thank you.

CHERYL C. SAENZ, resumed.

REDIRECT EXAMINATION

BY MR. WILLIAMS:

Q. Dr. Saenz, I just have a few clarifying questions if I could.

The first topic is the Savant study from 2018. It's an MDL Exhibit P-527. Plaintiffs' counsel showed you that article. Do you recall that?

A. Yes, I do.

Q. And you mentioned that it was a review article. Is that right?

A. That's correct.

Q. And what was the significance of your saying this is a review article?

A. Well, review articles are not peer-reviewed in the same sense as a primary study might be. So they are reading a bunch of different articles and putting together a summary. A review article is not bringing anything additional to the science itself because it's just summarizing what's already been published.

Q. Let me direct your attention to the portion of

the article that related to talc in particular. It's on page 5. There's a paragraph that begins with the word "talc." Do you see that?

A. Yes.

Q. What it says is:

"Talc is a silicate mineral, and exposure to it can cause inflammation of the ovaries and poses a risk hazard for development of EOC."

And there is a citation. Do you see that?

A. Yes.

Q. That citation No. 45, if we go to page 20 of Exhibit P-527, is to the Heller study. Is that right?

A. That's correct.

Q. That's the same Heller study we talked about a lot. Right?

A. That's correct.

Q. Does the Heller study provide evidence that talc causes ovarian cancer?

A. No, it does not.

Q. How about the second portion -- the first portion of the sentence that talc causes inflammation of the ovaries. Did the Heller study say anything about that?

A. No. In fact, the Heller study is that study you recall that looked at 24 women, 12 of whom reported

perineal application of talc, 12 of whom denied they had applied talc to their genitalia and found talc in the ovaries of all 24 women. Heller then went on to examine microscopically one of the ovaries for evidence of inflammation and found none.

Q. There was some discussion about diapering with respect to the Heller study. Do you remember that?

A. Yes.

MR. WILLIAMS: If we can pull up A 60, the Heller study, page 4 of 5, Table II, A 60 page 4, Table II.

Q. First a preliminary question: Do you happen to know, Doctor, the latency period for ovarian cancer -- 20, 30, 40 years? Do you happen to know what the literature says on that latency necessarily means to talk about whatever particular exposure you are talking about?

A. We don't really know what the latency is for any environmental exposure, and ovarian cancer, other than there is some suggestion from the asbestos literature that the latency for asbestos and the risk of ovarian cancer is somewhere around 20 to 25 years.

Q. If we look at this chart, if it were 20 to 25 years, and we look at the ages of the women involved in the study, that would suggest that they

were being diapered well after their infancy. Would that be accurate to say assuming a 20- to 30-year latency?

Let me back up. This is the Heller study and Table II listed the ages of the women who were studied. It said they had talc in their ovaries, some of them did and some of them didn't. Do you recall that?

A. Yes.

Q. Counsel on cross-examination suggested, isn't it true there are six of the women who said they remembered they were diapered in their infancy? Do you recall that cross-examination?

A. I recall that he said that. I don't remember that fact, but that's okay.

Q. Assume for purposes of the question that the study says that there were six women who said they were diapered in their infancy. If the latency period as you just described for asbestos that you've heard is 20 years --

THE COURT: You mean being diapered with baby powder.

MR. WILLIAMS: Yes, being diapered with baby powder.

THE COURT: They're all diapered I'm sure.

MR. WILLIAMS: Thank you, your Honor.

BY MR. WILLIAMS:

Q. If the women were the ages that are listed in Table No. 2 and the latency period, were as you described, that would mean they would have been diapered well after their infancy. Is that accurate?

A. You can say that or you can flip this and say many of these women, if they were diapered with baby powder, they are now of the age that at least 25 years have passed and we would expect to see in their ovaries either inflammation or ovarian cancer, if, indeed, that is the mechanism by which talc is inducing ovarian cancer.

Q. And what we do know about the Heller study is that half of the women reported that they had never used talc in the perineal area, but there was talc in their ovaries nevertheless. Correct?

A. That's correct.

Q. You were asked questions about the IARC monograph, and, specifically, it's Exhibit A 58. You read the monograph. Correct?

A. Which one are we talking about?

Q. You were asked questions about the Health Canada draft assessment. That's what I'm talking about now. Did you read that?

A. Yes.
Q. It's Exhibit A 58. Let me call up page 12, if I could. Do you recall reading this portion, the third paragraph, second full paragraph, that speaks about all of the various exposures that we have to talc.
A. Yes.
Q. It references here chewing gum, dried lagumes, rice, all the ways that we are exposed to talc in our lives. Do you remember that?
A. Yes.
Q. In the next paragraph it says that talc is present in approximately 8500 self-care products?
Do you see that?
A. Yes.
Q. Do you have an understanding as to whether talc, based upon your reading, talc is contained in vitamins or supplement pills that we take?
A. Talc is in almost every pill that we take, actually every prescribed medication. It's a component of all of those medications.
Q. What I'm getting at is, is there any basis for believing that the existence of talc in the body is necessarily associated with a woman's perineal use of talcum powder as opposed to the other manners in which we are all exposed to talc?

A. Right. There is no data, as we discussed really throughout most of the day today, that talc applied to the genital region makes it to the ovaries, and there are many other applications of talc that we put into our bodies on a daily basis.

Q. One of the exhibits that you were shown was the Langseth 2007 exhibit.

MR. WILLIAMS: For the record, your Honor, it was PSC Opposition Exhibit 5.

Q. Counsel showed it to you on the topic of migration. Do you recall that?

A. Yes.

Q. Let me direct you to the conclusion of the study. I'll just use the ELMO for this. This is PSC Opposition Exhibit 5, page 359.

A. Counsel, if I may, I believe that based on reading the abstract before, I told Mr. Dearing that I had no recollection, I couldn't recall as I sat here whether or not I had seen this paper before. And as I look at this table, it refreshes my memory. I have seen this paper before. I just want to clean up the record for that.

Q. I just wanted to direct your attention to the end of the paper that talks about it as a proposal to the research community. Is this the Langseth study

that you read that concluded here:

"The current body of experimental and epidemiological evidence is insufficient to establish a causal association between perineal use of talc and ovarian cancer risk."

A. Yes.

Q. Counsel showed you a Daniel Cramer study from I believe 2007. It's one you will recall he co-authored with Dr. Godleski from Harvard. Do you remember that line of questioning?

A. Yes.

Q. For the record, it's Exhibit P-SC Opposition Exhibit 76. Here is the cover page, Dr. Saenz.

I want to direct your attention to a statement contained on page 500 here. Do you see over in the right-hand column the authors wrote:

"Also we are not claiming that a causal relationship between ovarian cancer and talc use is proven for this case or in general."

Is that part of the same study that was put in front of you?

A. Yes, it is.

Q. Counsel put in front of you Blaustein's "Pathology of the Female Genital Tract." That was PSC Saenz 14.

I want to direct your attention to this page which counsel showed you under the heading "Inflammation." Counsel read the first few sentences here down to the word "carcinogenesis." You drew counsel's attention to the very first line that said "It has been suggested," and you pointed out that word. Do you remember that?

A. Yes, I do.

Q. I want to direct your attention to the sixth line, the sentence that begins "Evidence of pro-inflammatory microenvironment in endometriosis supports this hypothesis for Type I tumors."

Does the use of the word "hypothesis" make the point that you were making about this section on inflammation?

A. It does. I think what I stated was something very much along the lines of a suggestion is a hypothesis.

Q. And then below, under "Other Risk Factors," counsel read this portion that said:

"Other potential risk factors have been studied but associations with ovarian cancer risk are weak or inconclusive," and then it goes on to list a number of things.

My question to you is, is that consistent with

your reading of the literature with respect to talc in particular, that is, that any sort of an association is indeed weak and inconclusive with respect to causation?

A. I would take it further, counsel. I believe the odds ratio from the case control literature has shown a weak association in the range of 1.2 to 1.4. But I don't consider the literature inconclusive. I believe that it is conclusive right now in terms of the state of the science, and this is in part due to the fact that the cohort studies do not show an association. The case-control studies are inconsistent within and of themselves. There is no biologically plausible mechanism by which the talc would be inducing chronic inflammation.

Q. You were asked some questions about the U.C. San Diego website. Do you recall that?

A. About the U.C. San Diego website that they put up the questionnaire?

Q. That's right.

A. Yes.

Q. In the questionnaire that was put up counsel directed your attention to the name of a Dr. Richard J. LoCicero. Do you remember when that was placed up there?

A. He is not UCSD faculty.
Q. You know that because you know the UCSD faculty tree. Is that true?
A. That's true.
Q. Now, we looked over the break for Dr. LoCicero, Richard J. LoCicero. This indicates that he is from the Vanderbilt University. That's where he got his medical degree, and that he is affiliated, that he's an oncologist and hematologist. Do you see that?
A. Yes.
Q. Under hospital privileges down at the bottom, it references that he works out of Georgia. Right?
A. Right. So someone like him would be contacted by, say, a third-party vendor to write a document such as that, which has been posted on the UCSD website. He's essentially contracted to write those things. It's not reflective of what the UCSD faculty believes.
Q. Let me ask you some questions about the website, not the questionnaire portion, but the website that lists risk factors itself, if I could.
MR. WILLIAMS: If we can bring up exhibit Saenz 505?
Q. This document is not a quiz, is it? This is just a listing of risk factors?
A. Correct.

Q. And it describes "a risk factor is anything that may increase your chance of having a disease. Risk factors for certain types of cancer might include smoking, diet, family history, or many other things," and it lists things you should know about the risk for cancer. And there are three bullet points. See that?
A. Yes.
Q. None of those reference talc. Is that right?
A. That's correct.
Q. Down below there is a separate paragraph that says:

"Some risk factors, such as family history, may not be in your control, but other things you can change. Knowing the risk factors can help you to make choices that might lower your risk. For example, if an unhealthy diet is a risk factor, you may chose to eat healthy food," and it references weight and so on. Correct?
A. Yes.
Q. Under this portion of the website that lists risk factors for ovarian cancer, is talc listed?
A. No.
Q. Let me end by talking about the Berge case. Counsel asked you some questions.

For the record, it's Exhibit A 11.

I would like to direct your attention to page 9 of Berge and ask you this:

You have described how -- and counsel has put in front of you the forest plot where the point estimates are to the right of 1. Do you recall that?

A. Were we looking at Penninkilampi for that, I thought?

Q. Yes, we were. I'm not suggesting Berge did it. If we could go to the ELMO very quickly. This is the forest plot I believe that counsel placed in front of you on cross-examination. Do you recall that?

A. Yes.

Q. And he pointed to the odds ratios being to the right of 1. You remember that, right?

A. Right.

Q. My question going back to Berge, do you remember that Berge -- and this is page 9 of Exhibit A 11, left column.

Do you recall that that study talks about the notion of the predominance of the retrospective case-control studies as it relates to a meta-analysis?

A. Yes.

Q. And you see the sentence here, it says:

"Also, there were limitations not specific to our study, including" -- and then there is a list of a

few things, "the predominance of retrospective case-control studies."

Do you see that?

A. Yes.

Q. What do understand that to mean?

A. What that discussion is pertaining to is that there were many more women in the case-control studies than there were in the cohort studies. The volume of cases was in the case-control studies. The authors are also acknowledging that there was no external validation data, meaning that these women self-reported their main exposure of interest. They weren't interviews per se. They were women simply answering retrospectively about their talc use, and, essentially, the authors are basically discussing the biases that are inherent to the case-control studies.

Q. Just the sheer numbers, right. If there are 20 something case-control studies, then there are only a few of the cohort studies. Does that have an impact on this notion of predominance?

A. It does. It's dependent on not just the number of studies per se, although that influences it, but the women that were in -- the numbers of women in each of those studies as well, and the predominance favored the case-control studies.

Q. Now, let's end with the last page of this exhibit. It's actually page 10, just before the acknowledgements.

In the Berge study, after going through its analysis of which study to include and which not, the analysis of the cohort studies as well as the case-control study concluded:

"Several aspects of our results, including the heterogeneity of results between case control and cohort studies, however, do not support a causal interpretation of the association."

Did I read that right?

A. Yes.

Q. Based upon your review of the studies, the data, the information from the cancer watchdogs, if you will, and the organizations that you have reviewed, and based upon your experience for the last 25 years, is there a way reasonably to read that data as suggesting that there is a causal association between talc use and ovarian cancer that is consistent, that is strong, as opposed to weak and inconclusive and lacking in biological plausibility?

A. No, there is not, and the authors of Berge concur.

MR. WILLIAMS: No further questions, your

Honor.

THE COURT: Thank you.

RECROSS-EXAMINATION

BY MR. DEARING:

Q. Does your institution know or disclose on its website that the content is not reviewed for accuracy by staff physicians?

A. I don't know.

Q. Does your institution disclose on its website that the content may not be accurate?

A. I don't know.

Q. Does your institution disclose on its website that the content is meant for marketing and not for a woman's health?

A. I don't know.

Q. Were you aware your institution's website mentions talc as a possible risk factor for ovarian cancer before we had that conversation?

A. Before I had what conversation?

Q. Today with me when I asked you about your website.

A. No.

Q. Mr. Williams mentioned the Savant article. I think he suggested that there is no suggestion here

that talc causes inflammation and increases the risk of ovarian cancer, and I wanted to direct you back to it. So would you turn to 115. Let's look at page 6.

This is the inflammation model in Savant, and it identifies sources of inflammation in the ovary and fimbriae, and it talks about talc exposure right there. Right?

So would you agree this article does discuss and proposes that talc exposure to the ovary does create an inflammatory reaction which could be a precursor to cancer?

A. This is a cartoon graphic, if you will, again, for the hypothesis that talc exposure causes chronic inflammation. But this is still just their suggestions/hypothesis. This is not proof. This is not documentation of a mechanism.

Q. Since your working in California, are you familiar with the California Department of Public Health Occupational Health Cosmetic -- California Safe Cosmetics Program?

MR. WILLIAMS: Beyond the scope, your Honor.

THE COURT: Sustained.

BY MR. DEARING:

Q. Do you know whether the state of California recognizes talc as a carcinogen?

MR. WILLIAMS: Same objection.

THE COURT: Sustained.

BY MR. DEARING:

Q. You mentioned that there was no current or recent regression model that suggested that talc was a risk factor, and I wanted to draw your attention to the Wu study, which is a 2015.

A. I believe you are misstating my testimony. What I said is that there is no algorithm -- I think at the time we were looking at that paper from Lake Como, and what I said is there is no algorithm in clinical practice that you plug in risk factors to assess a woman's risk of ovarian cancer. There is nothing like that in clinical practice.

Q. Okay.

A. I didn't say other authors haven't published. I said nothing in clinical practice.

Q. I thought you said there was nothing recent.

A. I said there is nothing in clinical practice in 2019 that algorithm was suggested in 2007.

Q. This says:

"We used multivariate logistic regression to examine parity, oral contraceptive use, tubal ligation, endometriosis, family history of ovarian cancer, and talc use, and risk of invasive epithelial

ovarian cancer among Hispanics, African-Americans, and non-Hispanics Whites."

So that is exactly what the Wu scientists did; they created a multivariate logistic regression to look at those risk factors?

A. You are completely misrepresenting what this is.

Q. I am?

A. You are.

Q. We can read what it is.

A. This is not an algorithm to calculate a woman's odds ratio. The authors of this study sat down. The intent of their study was to look at the following risk factors: parity, oral contraceptive use, tubal ligation, endometriosis, et cetera, and calculate odd ratios for the risk of developing ovarian cancer. This is not an algorithm that is to be applied in clinical practice. You can poll every case-control study. You will see something in the methods section that talks about multivariate logistic regression that is the statistical technique to evaluate the influence or the odds ratio of each and every one of these risk factors on the development of ovarian cancer.

Q. I don't think you heard my question.

THE COURT: I don't think there was even a question, so let's go back, Doctor, and listen to his

question. He did not have one yet. All he had done was read what was in this study. So let's go back, please.

BY MR. DEARING:

Q. Isn't it true they used talc use as a risk factor to calculate the risk of invasive epithelial ovarian cancer? They list it right there?

A. They evaluated the use of talc and the risk of ovarian cancer, correct.

Q. You mentioned the Heller study on redirect. I just wanted to ask you something.

You remember in the Heller study one of the calculations they discovered when they were calculating the particle burden in the tissue was that the women who reported talc use actually reported about three times more -- actually was found to have about three times the particle burden of the women who did not use talc. Do you see that?

A. In five of the subjects, yes -- I'm sorry. Could you put that back up for a second?

Q. Yes.

(Pause.)

A. Yes.

Q. The five that reported talc use, five of the 12, they had almost three times the number of talc

particles as those with no reported talc use. Right?
A. Right. It was about 2.5 times, but, yes.
Q. Real quickly, can you pull up PSC 76, please. One more quick look at this Cramer study. This is the study Mr. Williams just mentioned, Cramer 2007.
He took you to the quote that says, "Essentially, this study doesn't establish that talc causes ovarian cancer." Do you remember that quote? I can find it exactly.
A. Correct.
Q. But you know this is a case note involving a 68-year-old woman. Right?
A. Okay.
Q. No reasonable scientist is ever going to suggest causation based on what they find in a single patient, are they?
A. No.
Q. And that was not the intent of the study?
A. I don't know the intent of the study other than it was to describe what their findings were.
Q. They were not trying to establish causation in that study, were they?
A. No. That's what they said in their discussion section, they weren't trying to establish causation.
Q. Because you cannot do that with one patient.

Right?
A. No responsible scientist would try to establish causation with one patient. That is correct.
Q. Isn't it true you did not complete a full Bradford Hill analysis when you were forming your causation opinions in this case?
A. So I did not complete a Bradford Hill analysis under the guise of describing it as a Bradford Hill analysis, but in my review of the literature and in the writing of my report I actually did look at many of the criteria.

In fact, I would say almost all of the criteria that are described in a Bradford Hill analysis. I looked for strength of association. I looked for consistency. I look for coherence. I looked for what I call dose-response, which I believe Bradford Hill refers to as biologic gradient.

I weighed all of the literature, the things that I reviewed very much along the lines of a Bradford Hill analysis.
Q. You would agree the Bradford Hill is generally-accepted as a method by which causation can be determined, right, or at least a causal association?
A. Yes.

Q. To do a complete Bradford Hill analysis you have to consider the totality of the evidence. Right? The totality of the studies, whatever you are researching?
A. Yes.
Q. Since you heard some of the testimony yesterday, do you agree that qualified, skilled scientists can conduct a Bradford Hill analysis and actually reach different conclusions at the end?
A. No, I don't agree with that because I think the methodology of the folks that have come to this room and testified that talc causes ovarian cancer, I think their methodology was flawed in the way that they conducted their analysis, because the only conclusion that you can draw is that talc does not cause ovarian cancer.
Q. If you do a thorough review, Doctor, you just said that a thorough complete Bradford Hill analysis requires consideration of the totality of the evidence.

Isn't it true that when you were formulating your opinion, you didn't consider the in vitro studies pertaining to talc?
A. That's not entirely true because I actually read Dr. Saed's experiments, and I also knew from your expert reports -- for example, the Shukla study and

Buz'Zard study did not show any evidence of malignant transformation. So I considered them in my analysis.

Additionally, one of the Bradford Hill criteria, which is experimental evidence, Bradford Hill in the actual document that is the Bradford Hill criteria, says that evidence of experimental evidence is not essential for a proper conduction of a Bradford Hill analysis.

Q. But you didn't read the cell studies, the Shukla studies, the Buz'Zard studies, the Saed studies?

A. I did read the Saed studies, that's incorrect.

Q. I believe you read the report of Dr. Saed. You didn't read his studies. Right?

A. That is his study. His report is his study. He testified to that in his deposition.

Q. You didn't read the other four studies. Correct?

A. The other four studies we talked about earlier?

Q. Yes.

A. I did not read those prior to writing my report but I did know what the content of them was, and it was not important to my analysis.

Q. One last question for you, Doctor: Based on the IARC assessment of asbestos and risk of ovarian cancer, I want you now to assume that there is

asbestos in Johnson & Johnson's talcum powder products. Is it your testimony that you would counsel your patients that it is safe, based on your review of the literature, to put that product containing asbestos on her genitals? Is that your testimony?

A. Yes.

MR. DEARING: Thank you. That's all I have.

MR. WILLIAMS: No questions, your Honor.

THE COURT: You are excused.

(Witness excused.)

THE COURT: Off the record.

(Discussion off the record.

THE DEPUTY CLERK: All rise.

(Court concluded at 4:00 p.m.)

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I N D E X

C E R T I F I C A T E

PURSUANT TO TITLE 28, U.S.C., SECTION 753, THE FOLLOWING TRANSCRIPT IS CERTIFIED TO BE AN ACCURATE TRANSCRIPTION OF MY STENOGRAPHIC NOTES IN THE ABOVE-ENTITLED MATTER.

S/Vincent Russoniello
Vincent Russoniello, CCR
Certificate No. 675

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